UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SOTHINATHAN SINNATHURAI, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. NOVAVAX, INC., STANLEY C. ERCK, GREGORY F. COVINO, JOHN J. TRIZZINO, and GREGORY M. GLENN, Defendants.	Civil Action No. TDC-21-2910 **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

Court-appointed Lead Plaintiffs Jeffrey A. Gabbert, Nuggehalli Balmukund Nandkumar, and David Truong ("Lead Plaintiffs"), individually and on behalf of all persons and entities who or which, during the period from February 24, 2021 through October 19, 2021, inclusive (the "Class Period"), purchased the publicly traded common stock of Novavax, Inc. ("Novavax" or the "Company") and were damaged thereby (the "Class")[1], bring this Consolidated Amended Class Action Complaint for Violations of the Federal Securities Laws against Defendants Novavax and several of Novavax's senior executives—President and Chief Executive Officer ("CEO") Stanley C. Erck, former Treasurer, Chief Financial Officer ("CFO") and Executive Vice President ("EVP") Gregory F. Covino, former CFO and current Chief Commercial Officer, Chief Business Officer, and EVP John J. Trizzino, and President of Research and Development Gregory Glenn (collectively, the "Individual Defendants").

Lead Plaintiffs' claims are brought upon personal knowledge as to their own acts, and upon information and belief as to all other matters, based upon, among other things, a review and analysis of: (1) reports and documents filed by Novavax with the Securities and Exchange Commission ("SEC"); (2) reports issued by analysts covering or concerning Novavax and its business; (3) press releases, news articles, transcripts, videos, and other public statements issued by or about Novavax, its business, and the Individual Defendants; (4) an investigation conducted by Lead Plaintiffs' attorneys, including interviews with former Novavax employees; and (5) other publicly available information concerning Novavax, its business, and the allegations contained

[1] Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer or director of Novavax during the Class Period; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; (v) Novavax's employee retirement and benefit plan(s) and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person.

herein. Lead Plaintiffs believe that substantial additional evidentiary support exists for the allegations herein and will continue to be revealed after Lead Plaintiffs have a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This securities fraud action arises out of Novavax's misleading statements made in connection with the Company's failed attempt to bring a vaccine candidate, NVX-CoV2373, to market during the Covid-19 pandemic. Specifically, Defendants misled investors about the vaccine's purported successful development, production, and imminent U.S. Food and Drug Administration ("FDA") approval; in reality, Novavax's vaccine was nowhere close to being approved for use: (a) because the vaccine's purity and potency numbers fell well below FDA safety requirements as a result of severe manufacturing problems including several undisclosed contamination events at its two U.S. manufacturing facilities; (b) because of a failure to manufacture the vaccine at scale; and (c) because of supply chain disruptions—all of which caused significant delays that jeopardized any chance Novavax had to capitalize on the market for Covid-19 vaccines.

2. Worse, Defendants personally made millions because of their rosy statements touting the successful vaccine development and manufacturing process that caused Novavax stock to remain at near record levels based on investors' belief that the Company was in pole-position to sell billions of doses in the near future. Indeed, just days before revealing bad news to the public about costly delays in Novavax's regulatory submissions due to the manufacturing problems, Defendant Erck sold over 100 thousand shares of Novavax stock, ***reaping proceeds of over $22.5 million for himself*** and leaving investors to take a massive hit. Likewise, Defendant Glenn ***made over $3 million in sales by selling thousands of shares right before the Company announced the regulatory delays***, which caused Novavax's stock price to plummet.

3. The truth about Novavax's failed vaccine candidate was finally revealed on October 19, 2021, when *Politico* released an article containing interviews with several Novavax employees detailing the extent of the Company's manufacturing problems, including the Company's inability to manufacture a vaccine that met the FDA's purity and potency requirements. The article also disclosed that Novavax's vaccine would likely not be approved until late 2022—almost a full year later. During the Class Period, ***Novavax's stock collectively fell over 50% in response to disclosures related to Novavax's manufacturing issues and inability to meet FDA requirements, thereby injuring investors***.

A. Novavax Attempts to Seize on the Massive Need for Covid-19 Vaccines

4. Novavax, headquartered in Gaithersburg, Maryland, is a biotechnology company that focuses on the development and commercialization of vaccines to prevent infectious diseases. At the beginning of the Covid-19 pandemic, Novavax found itself in a unique position to potentially capitalize on the urgent need for Covid-19 vaccines. Indeed, in early 2020, Novavax was granted a $1.6 billion government grant to manufacture millions of doses of its vaccine candidate for American citizens. But time was of the essence as Novavax was competing against other vaccine manufacturers such as Pfizer, Moderna, AstraZeneca, and Johnson & Johnson to get vaccines to the American public as quickly as possible.

5. If its vaccine was delayed too long, Novavax faced the significant risk of no existing need for that vaccine, which also would mean no longer being a candidate for rapid FDA approval and sale under an emergency use authorization ("EUA") mandate. As one analyst, CFRA, explained, "***[w]e think the future financial success of [Novavax] . . . is highly dependent on successful approvals and rapid commercialization of its Covid-19 vaccine***." And as another analyst, Zacks, noted, "***[a]ny delay in the study outcome or any developmental setback for . . .***

the COVID-19 vaccine candidate will be a major disappointment for [Novavax], leaving an adverse impact on its shares."

6. While EUA provides for an expedited pathway to approval, it still requires that the vaccine candidate meet certain basic safety and efficacy benchmarks imposed by the FDA, including current Good Manufacturing Practices ("cGMP"). As part of cGMP, Novavax's vaccine had to meet certain purity and potency levels and the Company had to ensure that its facilities were void of any contamination. Additionally, FDA regulations required Novavax's direct involvement with the manufacturing processes of its facilities and that it remained informed of any issues related thereto.

7. However, during the Class Period, Novavax simply could not manufacture vaccines at the required FDA purity and potency levels, experienced numerous contamination events in critical manufacturing facilities, failed to successfully scale up production, and faced supply chain disruptions—all of which caused material delays in Novavax's EUA filing. Indeed, multiple individuals who worked on the vaccine confirmed that Novavax was experiencing severe manufacturing problems that prevented the Company from timely releasing the vaccine to the public while demand still existed.

8. Two former employees who worked at Novavax's two primary vaccine manufacturing plants in Texas and North Carolina confirmed that the plants were struck with repeated contamination events that in some instances caused the manufacturing plants to be shut down (sometimes for months) while the contamination was investigated.[2]

[2] Novavax partnered with FUJIFILM Diosynth Biotechnologies ("FUJIFILM") to produce certain critical components of NVX-CoV2373 at FUJIFILM's manufacturing facilities in Texas (the "Texas Facility") and North Carolina (the "North Carolina Facility"). These plants were crucial to Novavax's ability to produce its vaccine candidate. Indeed, as Defendant Trizzino himself

9. For instance, the former Head of Technical Operations, Gene Therapy at the Texas Facility, CW 5, explained that a microbial contamination had existed there since December 2020 and occurred on at least four occasions. According to CW 5, these contamination incidents required shutting down the manufacturing lines for each incident of contamination found.

10. Compounding these problems, according to CW 5, ***the Texas Facility once again became so contaminated in March 2021 that the facility's manufacturing processes completely shut down from March 2021 until September 2021***. CW 6 similarly recalled that contamination had existed at the Texas Facility since April 2021, which caused its manufacturing processes to shut down until at least the end of CW 6's tenure on June 30, 2021. Moreover, an FDA investigation in March 2021 uncovered a microbial contamination at the Texas Facility that occurred in January 2021 but was improperly reported.

11. Moreover, according to the former Quality Assurance Manager at the North Carolina Facility, CW 7, some contamination issues spanned the "whole gamut" of the project (*i.e.*, throughout the entire Class Period), referring to manufacturing Novavax's vaccine candidate, and said they were "always an issue," which required FUJIFILM to discard the batch, ending the process.

12. In response to these events, the FDA inspected the Texas Facility and North Carolina Facility in March 2021 and April 2021, respectively, and confirmed that the two manufacturing facilities were experiencing severe manufacturing problems. In a 52-page investigation report and Form 483 issued to the Texas and North Carolina Facilities in March and April 2021, the FDA identified numerous quality-related problems and issues with the vaccine's

---

explained, the "***antigen produced at the Fuji sites in North Carolina and Texas are a critical component of our US supply chain***."

purity including that ***contamination was discovered and not properly recorded and investigated, including microbial contamination that was discovered in January 2021***; that the ***cleaning procedure for certain manufacturing areas was not always followed***; that employees ***failed to investigate for root causes and implement adequate corrective and preventative actions to control microbial contamination***; that there were ***inadequate procedures for the "Purification" step***; and that the ***manufacturing process was not adequately monitored and/or controlled to ensure the quality of the drug substance was not adversely affected***.

13. As a result, during the Class Period, ***Novavax was only able to manufacture vaccines with purity levels of around 70%—with some batches of vaccines containing purity levels of as low as 30%—nowhere close to the 90% purity level required by FDA standards***. Similarly, Novavax was unable to maintain the proper level of potency throughout 2021.

14. In addition, Novavax was not able to successfully scale up production throughout the Class Period. For instance, ***Novavax was not even able to produce the required number of doses in time for clinical trials to be performed on the drug***, which was then causing the trials to be delayed. Moreover, former Novavax and FUJIFILM employees confirm many supply chain problems—such as domestic supply constraints—at the Texas Facility, which its Director of Manufacturing, CW 6, recalled "were always a struggle" and an "ongoing issue." The North Carolina Facility likewise had difficulty procuring the components necessary to manufacture its Covid-19 vaccine, such as filters and resin used in the manufacturing process.

15. In addition to FDA regulations requiring Novavax to stay apprised of any problems that developed in any facility manufacturing its vaccine, multiple former employees from the Texas and North Carolina Facilities confirm and corroborate ***that Novavax was notified by the FDA and Novavax's manufacturing partners at the Texas and North Carolina Facilities of the***

manufacturing problems that occurred throughout the Class Period. For example, several former employees from the Texas Facility confirmed that Novavax had several onsite employees at that facility, and that ***they communicated with Novavax's onsite employees "every single day" regarding manufacturing, purity, and the results of quality checks***. The Quality Assurance Manager at the North Carolina Facility similarly explained that Novavax was notified of problems at the North Carolina Facility, including contamination. Indeed, the Quality Assurance Manager at the North Carolina Facility, CW 7, explained that the North Carolina Facility constantly communicated any problems to Novavax, which had someone onsite at the North Carolina Facility weekly at a minimum.

B. Defendants Tout That NVX-CoV2373 Was Aligned with FDA Criteria

16. Despite these significant problems related to purity, potency, contamination, scalability, and the supply chain, throughout the Class Period, Defendants falsely reassured investors that the manufacturing process was going smoothly and that Novavax was aligned with the FDA criteria (*e.g.*, certain purity, potency and other quality standards) needed for Novavax to file its EUA in a timely fashion. For example, on February 24, 2021, in an interview with *The Washington Post*, Defendant Glenn touted to investors that Novavax was "***aligned up with [the FDA's] success criteria in all of [Novavax's] trials***."

17. Analysts were encouraged by Defendants' reassurances. For example, Jefferies published an analyst report stating, "[a]ltogether, everything remains on track, including EUA filing in UK, EU and USA in Q2." Similarly, Zacks noted that the "vaccine is also advancing well." In fact, CFRA even issued a Strong Buy rating for Novavax and reported that "[w]e think 2021 could be a turnaround year for [Novavax]," and that "[w]e think [Novavax's] Covid-19 vaccine candidate is well-placed to receive the fourth EUA in the U.S. in Q2."

18. However, far from being "aligned" with the FDA's success criteria, Novavax was unable to meet the FDA's purity or potency criteria due to several manufacturing problems. Then, in May of 2021, Novavax disclosed that it would be delaying its EUA submission to the FDA. Specifically, on May 10, 2021, during market hours, *The Washington Post* reported that Novavax's EUA "filing was delayed by manufacturing regulatory issues, until June at the earliest." Novavax later that day, after market hours, confirmed that it was unlikely to seek an EUA for NVX-CoV2373 in the U.S. until July 2021 at the earliest—*i.e.*, the third quarter of 2021. As a result of this news, ***Novavax's stock price fell 8.81% on May 10, 2021***, and, following the Company's confirmation, ***continued to fall an additional 13.91% on May 11, 2021***.

19. Notably, knowing that Novavax shares would tumble with the announcement of any delay, some of the Individual Defendants decided to enrich themselves prior to announcing the delay to the public. For example, not long before announcing the EUA filing delay on May 10, 2021—an announcement that was certain to cause Novavax's stock price to plummet—in April 2021 (around the same time as one of the FDA inspections), Defendant Glenn cashed in over 8,000 shares for over $1.6 million in proceeds. Defendant Trizzino likewise sold over 3,000 shares on May 5 and May 7, 2021, just days before the announcement, to make nearly $600,000 in proceeds.

1. Defendants Reassure Investors That Novavax Overcame the Problems That Caused the Regulatory Delay

20. Yet, despite delaying its regulatory filing, Defendants continued to reassure investors that Novavax had resolved the challenges that caused the regulatory delay. Indeed, Defendant Erck told investors that "***nearly all of the major challenges have been overcome*** and we can clearly see the light at the end of the tunnel." Defendant Erck similarly touted, with respect to solving the manufacturing problems: "***I'm happy to say we did. We've crossed that bridge.***

We're—we made a big breakthrough there and we're now racing towards validating everything and putting it into a package."

21. Throughout the Class Period, Defendants continued assuring investors that any manufacturing problems were in the past through statements such as "***we've eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine***," "***we are well positioned with our technology and timing to supply product for boosting and seasonal revaccination***," and "***our trials proved that we are on the right track***"—leading investors to believe there was nothing to worry about in terms of manufacturing problems.

22. The market bought Defendants' story. Indeed, in light of Defendants' continued reassurances, an analyst from Jefferies noted that Novavax's management "remains confident in their ability to execute" and that, "[w]hile [filings with the FDA] took longer than they initially expected, it appears they have everything close to being set now." Cantor Fitzgerald also reported that despite Novavax's update, "according to management, facilities in its network have demonstrated the ability to manufacture commercial scale GMP material." And H.C. Wainwright explained that "[w]e believe the company remains a solid player in the COVID-19 vaccine landscape and think concerns about a delay in regulatory filings and manufacturing challenges are only temporary setbacks."

23. However, as with the previous quarter, as a result of the underlying manufacturing problems related to purity, potency, contamination, scalability, and the supply chain, on August 5, 2021, Novavax further delayed its EUA filing and reported that it expected to file for NVX-CoV2373's EUA in the fourth quarter of 2021, rather than the third quarter of 2021. On that same day, Novavax disclosed, "[t]he U.S. government has recently instructed ***the Company to prioritize alignment with the U.S. Food and Drug Administration on the Company's analytic methods***

before conducting additional U.S. manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made." As a result of this news, ***Novavax's stock price dropped 19.61% on August 6, 2021***. In response to this news, Seeking Alpha reported that the "news was a shocker for investors."

24. Once again knowing that the second delay would cause the stock to plummet, in July 2021, right before the Company's announcement of the delay—and ***during the very month the Texas Facility was shut down*** and being investigated by the FDA for contamination problems—***Defendant Erck sold over 100 thousand shares of Novavax stock worth over $22.5 million***. Similarly, Defendant Glenn sold over 8,000 shares in July 2021, resulting in over $1.5 million in proceeds.

2. Despite Consistently Delaying Novavax's EUA Filing Due to Manufacturing Problems, Defendants Again Reassure Investors That Such Problems Have Been Resolved

25. Defendants continued to conceal the full truth regarding the underlying manufacturing problems mentioned above, and again reassured investors that "***[w]e appear to have got past (certain) supply issues and are now being able to produce at scale***" and that "***we've been extremely transparent across multiple fronts***." Notably, on September 29, 2021, Defendant Trizzino continued to assuage investors that some challenges that Novavax faced "***have now been resolved***."

26. In light of Defendants' continued reassurances, analysts and the media remained optimistic. For example, despite finding that the delays were "less than ideal," Jefferies reported that "[m]anufacturing appears to be on track w[ith] the [C]ompany reiterating plans to reach 100M doses/month and 150M doses/month by the end of Q3 and Q4, respectively." Similarly, Jefferies explained, "the risk associated w[ith] these filings has been significantly reduced and [management] remains very confident they will be able to file." Additionally, Seeking Alpha

stated that "[w]hile [Novavax] announced a delay in submission to US FDA, it is still on track to achieve its previously planned manufacturing capacity for Q3 and Q4."

3. The Truth About the Failed Vaccine Candidate Is Revealed to Investors

27. Despite Defendants' false assurances throughout the Class Period, the truth was finally revealed to investors on October 19, 2021, when a *Politico* article reported a laundry list of manufacturing delays that had been preventing, and would continue to prevent, Novavax from filing its EUA in time. Notably, the article explained that Novavax's "issues are more concerning than previously understood" and that ***the Company could take until the end of 2022 to resolve its manufacturing problems and obtain the necessary regulatory authorizations and approvals***.

28. The *Politico* article revealed that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards" with respect to NVX-CoV2373. For instance, according to the article, the Company "has consistently run into production problems," including that "[t]he methods [Novavax] used to test the purity of the vaccine have fallen short of regulators' standards" and that a "person familiar with the [C]ompany's manufacturing process said Novavax has recently shown purity levels hovering around 70 percent"—still well below the 90% FDA requirement. Additionally, the article disclosed that Novavax was already aware of specific concerns with NVX-CoV2373's manufacturing process as U.S. officials had warned Novavax about issues related to meeting the FDA's rigorous quality standards once the vaccine went into mass production.

29. In response to this news, ***Novavax's stock price fell $23.69 per share, or 14.76%***, to close at $136.86 per share on October 20, 2021—further damaging investors. Additionally, *Politico* reported on October 20, 2021, that Novavax's issues were "worse than previously reported and could take several more months to set right."

II. JURISDICTION AND VENUE

30. The claims asserted herein arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5(a), (b), and (c) promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

31. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

32. Venue is proper in this District pursuant to 28 U.S.C. §1391(b)-(c), and Section 27 of the Exchange Act, because Novavax's headquarters are located in this District, the Company conducts substantial business in this District, and many of the acts and practices complained of herein occurred in substantial part in this District.

33. In connection with the acts, conduct and other wrongs alleged in this Complaint, the Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

A. Lead Plaintiffs

34. Lead Plaintiff Jeffrey A. Gabbert ("Gabbert") was appointed to serve as Lead Plaintiff in this action by Order of this Court dated January 26, 2022. ECF No. 47. As set forth in his Certification previously filed with the Court on January 11, 2022 (ECF No. 26-7), Lead Plaintiff Gabbert purchased Novavax common stock at artificially inflated prices during the Class Period.

35. Lead Plaintiff Nuggehalli Balmukund Nandkumar ("Nandkumar") was appointed to serve as Lead Plaintiff in this action by Order of this Court dated January 26, 2022. ECF No. 47. As set forth in his Certification previously filed with the Court on January 11, 2022 (ECF No.

26-7), Lead Plaintiff Nandkumar purchased Novavax common stock at artificially inflated prices during the Class Period.

36. Lead Plaintiff David Truong ("Truong") was appointed to serve as Lead Plaintiff in this action by Order of this Court dated January 26, 2022. ECF No. 47. As set forth in his Certification previously filed with the Court on January 11, 2022 (ECF No. 24-3), Lead Plaintiff Truong purchased Novavax common stock at artificially inflated prices during the Class Period.

B. Defendants

1. Corporate Defendant

37. Defendant Novavax is a biotechnology company that focuses on the discovery, development, and commercialization of vaccines to prevent serious infectious diseases and address urgent global health needs. To date, Novavax has never brought a successful candidate to market. Novavax is incorporated under the laws of Delaware with its principal executive offices located at 21 Firstfield Road, Gaithersburg, Maryland 20878. Novavax's common stock trades on the NASDAQ exchange under the symbol "NVAX."

2. Individual Defendants

38. Defendant Stanley C. Erck ("Erck") has served as the Company's President and Chief Executive Officer since April 2011 and as a member of the Company's Board of Directors since June 2009. In his role as President and CEO of Novavax, Defendant Erck participated in earnings calls and conferences with securities analysts, during which he made false and misleading statements and omissions of material fact relating to the Company's ability to manufacture the NVX-CoV2373 vaccine in conformance with FDA and cGMP requirements. Defendant Erck also sold 197,008 shares of Novavax stock during the Class Period for proceeds of $38,672,789. In addition, during the Class Period, 3,162 shares of Erck's Novavax stock, worth $784,682, were

withheld by the Company to pay for his personal taxes or the exercise price in connection with Company-issued stock.

39. Defendant Gregory F. Covino ("Covino") served as Novavax's Chief Financial Officer ("CFO"), Treasurer, and an Executive Vice President ("EVP") of the Company from November 16, 2020 until April 12, 2021.

40. Defendant John J. Trizzino ("Trizzino") served as Novavax's Interim CFO from April 12, 2021 to August 16, 2021. Trizzino also serves as the Company's Chief Commercial Officer, Chief Business Officer, and an EVP of the Company. Defendant Trizzino participated in earnings calls and conferences with securities analysts, during which he made false and misleading statements and omissions of material fact relating to the Company's ability to manufacture the NVX-CoV2373 vaccine in conformance with FDA and cGMP requirements. Defendant Trizzino also sold 54,635 shares of Novavax stock during the Class Period for proceeds of more than $12,013,325. In addition, during the Class Period, 2,691 shares of Trizzino's Novavax stock, worth $601,692, were withheld by the Company to pay for his personal taxes or the exercise price in connection with Company-issued stock.

41. Defendant Gregory M. Glenn ("Glenn") has served as Novavax's President, Research and Development since March 2016. On February 24, 2021, Defendant Glenn participated in an interview with *The Washington Post* to discuss Novavax's regulatory timeline for its EUA and Novavax's progress thus far in meeting FDA requirements, during which he made false and misleading statements and omissions of material fact relating to the Company's ability to manufacture the NVX-CoV2373 vaccine in conformance with FDA and cGMP requirements. Defendant Glenn also sold 77,862 shares of Novavax stock during the Class Period for proceeds of more than $14,508,912. In addition, during the Class Period, 14,106 shares of Glenn's Novavax

stock, worth $2,703,649, were withheld by the Company to pay for his personal taxes or the exercise price in connection with Company-issued stock.

42. Defendants Erck, Covino, Trizzino, and Glenn are referred to herein as the "Individual Defendants." Defendant Novavax and the Individual Defendants are referred to herein, collectively, as "Defendants."

3. Relevant Third Parties[3]

43. **Confidential Witness ("CW") 1** worked for Novavax from December 2020 to August 2021 as a Manager – Regulatory Affairs CMC (Chemistry, Manufacturing and Controls). CW 1 worked remotely from the Washington, D.C. area. She reported to Senior Director – Regulatory Affairs CMC Jannine Haberman Cobb, who ultimately reported to Director – Regulatory Affairs Kathleen Callahan. Callahan reported to Senior Vice President/Chief Regulatory and Quality Officer Henrietta Ukwu. At Novavax, CW 1 helped manage manufacturing sites contracted by Novavax to produce its Covid-19 vaccine. Further, as part of her role on the Regulatory Affairs CMC team, CW 1 helped Novavax put together documents containing information from the Company's manufacturing sites that was then submitted to the FDA in the form of Module 3 Quality reports. CW 1 explained that the FDA communicated concerns about the stability of Novavax's vaccine batches one or two times, possibly in December 2020 and then again in March 2021.

44. **CW 2** worked at Novavax from January 2021 until October 2021 as a Medical and Communications Publications Specialist. She reported to Director – Medical Communications and Publications Betsy Kitchens, who reported to Vice President – Clinical Development,

[3] All Confidential Witnesses are referred to with female pronouns, regardless of gender, to protect their identity.

Coronavirus Vaccines Seth Toback. Toback reported to Chief Medical Officer Filip Dubovsky. CW 2 explained that her role was part of a "new and small team called Medical Affairs" that Novavax created as it began ramping up its "production headcounts to prepare to produce the [Covid-19] vaccine." The Medical Affairs team had about five or six people when CW 2 joined but grew to about 11-12 members. CW 2's role was to create scientific materials and supporting publications for primary manuscripts and secondary manuscripts for the ongoing clinical trials. She explained that whenever Novavax produced data to present, the Medical Affairs team worked on publications and submitted to peer-reviewed journals.

45. **CW 3** worked at Novavax from November 2020 until April 2021 as a Laboratory Technician. She worked out of a facility in Gaithersburg, Maryland. CW 3 conducted product improvement testing that the Company planned to use in later phases of its Covid-19 vaccine manufacturing process. Her role also involved tasks such as cleaning, tidying and organizing, along with conducting experiments. According to CW 3, the work she did was all about improving the quality of the product and making sure the Laboratory Technicians were using the products made to their highest efficiency and to have the products be as concentrated as possible so that when the product was used it would be used as efficiently as possible. CW 3 further explained that the testing was designed to achieve the "most purity" and to determine "how to get higher purity at different filtration levels." She also explained that part of her work was to improve the processing as they were finding when they were making the vaccine that there were a lot of waste products.

46. **CW 4** worked at Novavax from July 2020 to October 2021 as a Senior Director – Clinical Operations, a role that involved overseeing the company's U.K. clinical trials for its Covid-19 vaccine. CW 4 reported to Vice President – Clinical Operations Patty Reed, who

reported to Chief Medical Officer Filip Dubovsky. CW 4 explained that Reed managed Novavax's Operation Warp Speed group. According to CW 4, Novavax struggled to produce enough proper vaccine doses for several different clinical trials, including about 4,000 doses needed for three smaller clinical trials in 2021, causing the trials to be delayed. In regard to the reasons for the delay in producing enough proper vaccine doses for the clinical trials, CW 4 said she was told that the Company was "delayed in manufacturing" due to issues with "lesser potency" and "stability" of the vaccines. CW 4 explained that these delays were experienced by those at Novavax working on Operation Warp Speed in the United States. She further stated that there were issues with the potency of vaccines "off and on" throughout 2021.

47. **CW 5** was formerly employed by FUJIFILM at the company's College Station, Texas location from September 2020 to October 2021 as Head of Technical Operations, Gene Therapy. CW 5 reported to current Senior Director - Gene Therapy and Vaccines, Eric Dul. CW 5 advised that in this role she ran technical operations that supported manufacturing at two of the three centers at the College Station location, and that one of these was the center used for manufacturing Novavax's Covid-19 vaccine, and the other was used for gene therapy. She further advised that her responsibilities also included oversight of the processes, equipment, engineers, compliance coordinators, and low-level mediation at those two centers. CW 5 explained that quality checks on vaccine manufacturing were conducted every 24 to 48 hours, adding that she and CW 6 communicated with the two onsite Novavax employees "every single day" regarding manufacturing and the results of quality checks. CW 5 added that due to the rush to get the vaccine to market, FUJIFILM hired many new employees who had little or no previous vaccine manufacturing experience, which was at least partly responsible for those delays. She also recalled four contamination incidents that led to delays in manufacturing that started between December

2020 and March 2021. According to CW 5, the first three were due to bacterial contaminations, or deviations, and the fourth and significantly more serious one was a viral contamination that was discovered on March 18, 2021, which caused a shutdown in manufacturing from then until around September 2021. CW 5 explained that Novavax employees and the FDA were notified about each of the contaminations

48. **CW 6** was formerly employed by FUJIFILM at the company's College Station, Texas location from July 2020 to June 30, 2021 as Director of Manufacturing, and her previous title was Manager Upstream Manufacturing from September 2018 to July 2020. CW 6 worked on the manufacturing of vaccines while at FUJIFILM, including Novavax's Covid-19 vaccine. CW 6 recalled that there were two delays in manufacturing the Novavax Covid-19 vaccine due to contaminations that occurred in December 2020 or January 2021 and around late April 2021. She further recalled that these delays occurred because of contaminations that occurred in the upstream part of the process. CW 6 further recalled that the resumption of manufacturing—that had been shut down due to the April 2021 contamination—kept getting pushed back and that it had still not restarted by the time her tenure ended on June 30, 2021. CW 6 also recalled that Novavax "knew everything that we were doing."

49. **CW 7** was formerly employed by FUJIFILM from January 2013 through November 2021 at the North Carolina Facility and was based in Durham, North Carolina. She worked as a Manager, QA (Ops. & Quality Life Cycle Management), and her responsibilities included quality assurance, as well as to ensure that projects were adhering to FDA regulations and internal procedures. CW 7 explained that FUJIFILM sometimes changed the vaccine manufacturing materials given supply chain issues and Novavax would have to approve all the changes. CW 7 recalled that Novavax had teams of people from departments including quality

and technical who were involved in any modifications. CW 7 also recalled that the contamination problems at the North Carolina Facility spanned the "whole gamut" of the project, referring to manufacturing Novavax's vaccine candidate, and said they were "always an issue." CW 7 further recalled that any problems were constantly communicated to Novavax, which had someone onsite at the North Carolina Facility weekly at a minimum.

50. **CW 8** was formerly employed by FUJIFILM from February 2016 through January 2021. CW 8 worked as a Quality Control Analyst, and her primary responsibilities were reviewing test methods and serving as a liaison between the quality control group and analytical development group. CW 8 was based out of Morrisville, North Carolina and worked on Novavax's Covid-19 vaccine. CW 8 explained that the vaccine was being produced under an accelerated timeline, and FUJIFILM would have to alter their processes "almost constantly." For example, CW 8 further advised that because of the speed of the process, the quality control team once had to send the test methods used to test the product back to the analytical development team in order to include additional details. CW 8 explained that the lapses were the result of certain steps being skipped in favor of an accelerated production timeline. CW 8 added that early analysis steps were skipped or done concurrently rather than being done prior to the production phase.

IV. SUBSTANTIVE ALLEGATIONS OF FRAUD[4]

A. Novavax's Business

1. Novavax Prior to the Covid-19 Pandemic

51. Novavax, headquartered in Gaithersburg, Maryland, is a biotechnology company that focuses on the discovery, development, and commercialization of vaccines to prevent serious infectious diseases and address urgent global health needs. Today, the Company's product

[4] Unless otherwise noted, all references to Novavax's business and operations refer to events that occurred during the Class Period as defined herein.

candidates include, among others, NVX-CoV2373, which is in development as a vaccine for Covid-19. But that was not always the case.

52. Novavax has historically focused on manufacturing vaccines for novel viruses and infections. For example, prior to Covid-19, the Company tried to develop vaccines for HIV, SARS, swine flu, and the Ebola virus. However, each of the vaccines either failed in testing or the epidemics ebbed, reducing the need for Novavax's vaccine candidates.

53. Prior to the Covid-19 pandemic, to avoid going out of business, Novavax sold all of its manufacturing facilities in 2019. At the beginning of 2020, there were only about 150 employees left at the Company. As of January 2020, Novavax had enough cash to survive only another six months, its shares traded under $4, with a market value of only $127 million, and it therefore risked being delisted from the NASDAQ stock exchange. But beginning in early 2020, the Covid-19 pandemic surfaced, providing Novavax with a golden opportunity to finally bring a vaccine to market and dig itself out of the financial ruin it had found itself in at that point.

2. Novavax Announces NVX-CoV2373 as a Possible Vaccine Candidate

54. On February 26, 2020, Novavax announced that it was developing a vaccine to protect against Covid-19. To support Novavax's efforts to develop a Covid-19 vaccine, the Coalition for Epidemic Preparedness Innovations ("CEPI")[5] awarded Novavax initial funding of $4 million on March 10, 2020. And on April 8, 2020, Novavax announced that its coronavirus vaccine candidate, NVX-CoV2373, which it claimed was a stable, prefusion protein made using Novavax's proprietary nanoparticle technology, would initiate a first-in-human trial in mid-May.

[5] CEPI is a global partnership among public, private, philanthropic, and civil society organizations that work together to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.

55. NVX-CoV2373 was Novavax's ticket out of years and years of financial hardship and repeated failed attempts of bringing a drug to market. Indeed, the Company's future viability depended on the vaccine's success. For instance, one analyst, CFRA, even reported that "the main focus of the [C]ompany is on its NVX-CoV2373 vaccine candidate against Covid-19," and that "[w]e think the future financial success of [Novavax] and its ability to record a positive bottom-line result is highly dependent on successful approvals and rapid commercialization of its Covid-19 vaccine."

3. Novavax Contracts with the United States Government to Produce Millions of Doses for Americans

56. In an effort to ramp up vaccine production in the United States, in April 2020, the government initiated Operation Warp Speed. Operation Warp Speed was designed to facilitate the development, manufacturing, and distribution of Covid-19 countermeasures. These projects were to be divided among components of the (i) Department of Health and Human Services, including the Centers for Disease Control and Prevention, FDA, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority; (ii) the Department of Defense ("DoD"); (iii) private firms; and (iv) other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.

57. On June 4, 2020, Novavax entered into a contract with the DoD for the manufacture of NVX-CoV2373. With funding provided by the Defense Health Program, the government agreed to fund up to $60 million to support Novavax in its production of several components of the vaccine in the United States. According to the DoD contract, Novavax was required to "establish within the United States large scale production" of one of NVX-CoV2373's major components. The DoD contract similarly required Novavax to "establish a production capability within the United States" for that same component. The terms of the agreement further demanded

Novavax to deliver 10 million doses of NVX-CoV2373 to the DoD by December 2020 so long as the vaccine was approved by the FDA.

58. Then, on July 7, 2020, Novavax chose to join Operation Warp Speed. As a result, the government awarded Novavax $1.6 billion to complete late-stage clinical development, including a Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373 as early as the end of 2020. As part of the agreement, Novavax was required to demonstrate that it could rapidly set up large-scale manufacturing and transition into ongoing production, including the capability to stockpile and distribute large quantities of NVX-CoV2373 when needed.

B. Novavax Continues Developing NVX-CoV2373 and Partners with FUJIFILM Diosynth Biotechnologies

59. Because the Company did not have manufacturing facilities of its own, Novavax entered into partnerships with companies to manufacture and produce its vaccine under Novavax's direction. For example, on July 23, 2020, Novavax contracted with FUJIFILM to manufacture bulk drug substance for NVX-CoV2373 at the Texas Facility and North Carolina Facility.[6]

60. The Texas Facility and North Carolina Facility were critical to Novavax's development of NVX-CoV2373, and thus the Company's success. For example, on February 19, 2021, Defendant Trizzino himself provided testimony in the form of a report to the Subcommittee on Oversight and Investigations, U.S. House of Representatives, Committee on Energy and Commerce to discuss Novavax's development of and U.S. manufacturing operations for NVX-CoV2373. In that report, Defendant Trizzino stated that the "antigen produced at the Fuji sites in

[6] The Texas and North Carolina Facilities are FUJIFILM's two U.S.-based manufacturing facilities and were the only two manufacturing facilities in the United States that were producing the antigen component of NVX-CoV2373—a necessary component for producing any vaccine.

North Carolina and Texas are a critical component of our US supply chain." Likewise, FUJIFILM CEO Martin Meeson referred to FUJIFILM as "a critical partner to Novavax."

61. During the same time as Novavax's rapid expansion, the FDA granted Fast Track Designation for NVX-CoV2373, "reflect[ing] the urgent need for a safe and effective vaccine to prevent COVID-19," as Defendant Glenn explained in Novavax's November 9, 2020 press release. According to the FDA, Fast Track is a process designed to facilitate the development, and to expedite the review of, drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

62. Shortly thereafter, on February 4, 2021, Novavax announced that it had begun the rolling review process for authorization of NVX-CoV2373 by multiple regulatory agencies. Novavax explained that the "reviews will continue while the [C]ompany completes its pivotal Phase 3 trials in the United Kingdom (U.K.) and United States (U.S.) and through initial authorization for emergency use granted under country-specific regulations." As part of the rolling review, Novavax explained that it would continue to submit additional information, including clinical and manufacturing data, to the agencies. That same month, Novavax announced the complete enrollment of PREVENT-19, its pivotal Phase 3 study in the United States and Mexico to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373.[7]

[7] PREVENT-19—which is being conducted with support from the U.S. government partnership, *i.e.*, Operation Warp Speed—is a randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M in up to 30,000 subjects 18 years of age and older compared with placebo. Two thirds of the participants are assigned to randomly receive two intramuscular injections of the vaccine, administered 21 days apart, while one third of the trial participants receive placebo. Trial sites were also selected in locations where transmission rates were high to accelerate the accumulation of positive cases that could show efficacy. PREVENT-19 stands for PRE-fusion protein subunit Vaccine Efficacy Novavax Trial COVID-19.

C. Novavax Was Required to Comply with Strict FDA Regulations

63. At every step of the development and manufacturing processes, Novavax was required to meet strict FDA standards including FDA cGMP. Indeed, Novavax's June 4, 2020 contract with the U.S. government specifically states that Novavax "shall manufacture enough bulk drug substance to produce ten million doses of vaccine drug product, ***all under current Good Manufacturing Practices*** and compatible with use in a late stage development clinical evaluation or Emergency Use Authorization." The contract similarly requires that Novavax "***shall ensure all quality control/assurance adhere to phase appropriate [current] Good Manufacturing Practices[] to ensure product quality and availability for use of the doses produced***."[8]

64. cGMP is a set of regulations enforced by the FDA, which provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.

65. Specifically, cGMP regulations require companies manufacturing and preparing drug products for administration to humans—such as Novavax—to establish a "quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors

[8] Likewise, according to Attachment A, Statement of Work, for an agreement between the U.S. government and Novavax entitled, "Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus," one of the manufacturing requirements was for the "[e]stablishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211."

have occurred, that they have been fully investigated." 21 C.F.R. §§ 211.1(a) and 211.22(a) (2022); *see also* 21 C.F.R. § 210.1 (2022).

66. FDA regulations state that the "***quality control unit shall be responsible for approving or rejecting drug products manufactured***, processed, packed, or held ***under contract by another company***." 21 C.F.R. § 211.22(a). The ***quality control unit also has "the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product***." 21 C.F.R. § 211.22(c).

67. Novavax was thus required to comply with the FDA's cGMP regulations, regardless of whether it developed and manufactured NVX-CoV2373 in-house at its own facilities or at its partners' facilities. Additionally, according to such cGMP regulations, Novavax was required to—and did—maintain direct involvement in the manufacturing process taking place in its partners' facilities, stay apprised of issues that develop in such facilities, and even advise on overall solutions to such issues.

68. According to the Director of Manufacturing at the Texas Facility, CW 6, Novavax had quality control employees and/or consultants onsite at the Texas Facility. CW 6 also recalled that other Novavax employees periodically visited the site, too. Head of Technical Operations, Gene Therapy, CW 5, similarly stated that Novavax had several employees and/or consultants on site, whom CW 5 identified as Technology Transfer Engineer Patrick Hash and Contractor Elizabeth Wang ("Novavax's Onsite Employees"). Indeed, CW 5 explained that CW 5 and CW 6 communicated with the Novavax's Onsite Employees "every single day" regarding manufacturing and the results of quality checks. CW 5 recalled that quality checks on vaccine manufacturing were conducted every 24 to 48 hours.

69. For example, as explained in more detail below, CW 5 recalled that Novavax's Onsite Employees were notified about each contamination issue that occurred at the Texas Facility throughout the Class Period. In fact, CW 5 further recalled that one of Novavax's Onsite Employees, Mr. Hash, was also involved in the investigations into the contaminations. CW 5 recalled that there were phone calls and emails about contaminations and delays from Mr. Hash to Novavax headquarters, including Novavax's Quality Assurance department. Further, according to CW 6, Novavax's Onsite Employees and others at Novavax's headquarters "knew everything that we were doing." CW 6 added that Novavax's Onsite Employees were on the Texas Facility's manufacturing floor during "all critical processes."

70. Similarly—and with respect to a particular viral contamination that occurred in March 2021 and ultimately shut down the Texas Facility's manufacturing processes until September 2021—CW 5 confirmed that every detail to do with the viral contamination was "communicated to" Novavax's Onsite Employees as the discovery and investigation progressed, along with daily calls with Novavax personnel in Novavax's headquarters in Maryland.

71. cGMP regulations further require companies such as Novavax to establish procedures "to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§ 211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the [FDA], or any regulatory actions relating to good manufacturing practices brought by the [FDA]." 21 C.F.R. § 211.180(f). For example, with respect to Section 211.198, cGMP regulations require companies to establish written procedures with respect to all drug product complaints, which "shall include provisions for review by the quality control unit, of

any complaint involving the possible failure of a drug product to meet any of its specifications." 21 C.F.R. § 211.198(a).

72. Moreover, cGMP regulations require companies to maintain laboratory records that "shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays," including a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194(a), (a)(6).

73. cGMP regulations also require companies to maintain and follow written procedures "designed to prevent objectionable microorganisms in drug products," and that are "designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products." 21 C.F.R. § 211.113; 21 C.F.R. § 211.56(c).

D. Undisclosed Manufacturing Problems Were Causing Delays—Preventing Novavax from Timely Filing Its EUA with the FDA

74. Throughout the Class Period, and unbeknownst to investors, Novavax consistently ran into manufacturing and production problems, which included: (a) both the Texas and North Carolina Facilities experiencing repeated contamination outbreaks; (b) Novavax failing to meet certain FDA quality standards for purity and potency levels for its vaccine; (c) failing to successfully scale up production; and (d) experiencing supply chain disruptions—all of which caused repeated delays in Novavax filing its EUA.

1. Sources Within Novavax Confirm That the Manufacturing Problems Were Causing Delays

(a) Rampant Contamination Events Repeatedly Set Back Production at the Texas and North Carolina Facilities

75. Throughout the Class Period, Novavax experienced repeated contamination outbreaks in critical facilities that were manufacturing NVX-CoV2373, which led to numerous FDA inspections and lengthy delays in order to rectify the contamination issues. CW 5 recalled multiple incidents of contamination in the Texas Facility since December 2020, and CW 6 similarly recalled contamination in the Texas Facility since either December 2020 or January 2021. Specifically, CW 5 recalled four contamination incidents that led to delays in manufacturing that started between December 2020 and March 2021 (the latter ultimately shut down the manufacturing processes until at least September 2021).

76. CW 5 recalled that the first contamination incident occurred in December 2020. CW 5 further recalled that the next incident followed about two or three months later, *i.e.*, in February 2021 or March 2021. CW 5 explained that when each contamination was discovered, the investigation into finding the source of those contaminations began with shutting down development and interviewing the staff involved in the manufacturing process.

77. According to CW 5, the first three contamination incidents were caused by bacterial contaminations, or deviations. Regarding the three bacterial contaminations, CW 5 described the first one as involving a "human factor," as an employee failed to follow proper procedures, and the next one related to the re-use of blades that were supposed to be only used one time.[9] Regarding the first contamination, which occurred in December 2020 and occurred in the upstream process, CW 5 recalled that the investigation revealed that one of the staff took it upon him or herself to

[9] CW 5 further advised that blades are heated up and used to connect two bags via various plastic tubes hanging from the bags.

remove a bag (somewhere along the process), drain it, and then reattached it when the bag should have been discarded and replaced with a new one. CW 5 further advised that the other three contaminations also occurred in the upstream part of the process.[10]

78. CW 5 explained that the next bacterial contamination occurred two or three months later when it was discovered that a blade was used multiple times, when these blades were meant to be one-offs, or used only once and then discarded according to standard operating procedure ("SOP"). CW 5 also recalled that there were difficulties in acquiring the necessary number of different components used in the manufacturing process due to global supply chain issues, and CW 5 recalled this including a lack of these blades. CW 5 assumed that the reusing of these blades had been going on for "several" weeks before it had been discovered.

79. CW 6 recalled that one contamination occurred due to a leak in a bag used as part of a bioreactor, and that there were one or two other bacterial contaminations. CW 6 further recalled that these delays occurred because of contaminations that occurred in the upstream part of the process.

80. Similarly, according to CW 7, contamination also existed at the North Carolina Facility during her tenure (which encompassed the entire Class Period) in the upstream process, which required FUJIFILM to discard the batch, ending the process. Furthermore, in discussing certain contamination issues that persisted at CW 5's facility throughout the Class Period, CW 5 also explained that depending upon where a contamination occurs in the process, the process may

[10] According to CW 5, all of the contaminations were occurring in the upstream process. CW 5 explained that, generally, the upstream process includes creating and building up the quantity of cells—cell growth and vaccine quantity. CW 5 explained that the downstream, or purity, process included purifying what had been created in the upstream process. CW 5 further explained that contamination in the upstream process usually reveals itself within 24 to 48 hours of it occurring and can often be revealed by a strong and unpleasant odor alone.

have to start back at step one again. As CW 5 explained, they would need to "dump the run . . . game over."

81. The repeated contamination events at both the Texas and North Carolina Facilities had an adverse impact on the vaccine's purity levels. Prior to and during the Class Period, Novavax's repeated contamination events prevented the Company from achieving the levels of purity and potency required by the FDA and thus significantly delayed its EUA submission.

(b) NVX-CoV2373 Failed to Meet FDA Purity and Potency Standards Which Delayed the EUA Filing

82. Throughout the Class Period, Novavax was unable to achieve certain purity and potency criteria required by the FDA, which prevented Novavax from filing its EUA. According to *Politico* articles published on October 19, 2021 and October 29, 2021, which cited the statements of multiple U.S. government officials and other individuals with direct knowledge of Novavax's manufacturing problems during the Class Period, by the end of the Class Period in October 2021, Novavax was only able to achieve approximately a 70% level of purity—far below the 90% required by the FDA—with some batches of vaccines containing purity levels of as low as 30%. The October 29, 2021 *Politico* article quoted one former U.S. government official who stated that "[f]or weeks and weeks and weeks the team assigned to Novavax would come back, and they'd always be talking about lack of purity . . . it got to be a little bit tedious"—referring to a team of Operation Warp Speed officials working with Novavax. The October 19, 2021 article further quoted individuals stating that Novavax "rushed the process," and that "the efficacy [of the vaccine] was never going to outweigh the risk associated with the impurity that was in there."

83. Novavax's critical problems with purity issues are corroborated by CWs who worked directly on Novavax's vaccine candidate; these CWs confirmed that the purity issues delayed the filing of Novavax's EUA. For instance, CW 3, who ensured the products at Novavax

were used efficiently and to also test them for purity, explained that Novavax experienced delays in sourcing raw materials "that did slow down our work."

84. Novavax was also unable to maintain the proper level of potency, which further delayed the regulatory process. For example, CW 4 recalled that the Company was "delayed in manufacturing" due to issues with "lesser potency" and "stability" of the vaccines. CW 4 provided the following hypothetical: "Manufacturing a vaccine is like baking a cake. You have a recipe for a cake, but you have to do it consistently. And if you start jumping around to manufacturers, when you change them, they have to make the cake the same way . . . . If they are off, then you have an issue. That can affect potency, stability. That was coming into play."

85. CW 4 recalled that the issues with potency of vaccines occurred "off and on" throughout 2021. CW 4 learned about the manufacturing problems—including with potency and stability—causing the delays when these issues were presented to a "broad group" at Novavax that included Reed and Dubovsky, as well as "everyone" who reported to Dubovsky to discuss their own respective studies. CW 4 further explained that also on the calls were people from Quality Assurance, Regulatory, and other departments. CW 4 also recounted that she learned about the delays in filing for the EUA during internal Novavax meetings.

(c) Novavax Failed to Successfully Scale Up Production

86. As a result of some of these issues, Novavax was also unable to produce enough viable doses to use for clinical trials of NVX-CoV2373. Novavax's inability to scale up NVX-CoV2373 production also contributed to delays in filing its EUA with the FDA. For example, CW 2, who was part of Novavax's Medical Affairs team, explained that she learned from colleagues that the Company was not efficient at producing vaccines at a scale that would be needed for mass production. CW 2 further explained that "we saw these delays over and over, and employees at Novavax [were] also frustrated."

87. For example, CW 4 recalled that Novavax struggled to produce enough proper vaccine doses for several different clinical trials, including about 4,000 doses needed for three smaller clinical trials in 2021, causing the trials to be delayed. CW 4 explained that in addition to the initial clinical trials Novavax conducted in the U.K. and the U.S. (which involved 15,000 and 30,000 subjects, respectively, requiring two doses for each subject), the Company wanted to start additional trials as new Covid-19 variants surfaced.

88. CW 4 further explained that there were at least two other studies that were being planned, adding that the studies were "delayed" and then scheduled to begin after October 2021. To this end, CW 4 stated: "Why am I seeing on the news that you're promising umpteen million doses and we can't secure 3,000 doses" for clinical trials. CW 4 explained that she learned about the shortage of vaccine doses for clinical trials from Associate Director – Clinical Supplies, Patrick Newingham. CW 4 said that she and her colleagues would inform Newingham that they needed a certain number of doses for the clinical trials.

89. Notably, CW 4 explained that if there were issues in getting a trial started, those problems would be brought to Filip Dubovsky and Defendant Erck. CW 4's understanding of how such information would have flowed up the chain of command at Novavax was that manufacturing issues were brought to Dubovsky's attention, that Dubovsky would have discussed it with Defendant Erck who in turn would have discussed it with Defendant Glenn, and that Defendant Erck—or sometimes Defendant Glenn—had to bring it to the attention of Novavax's Board of Directors.

90. CW 5 explained that due to the rush to get the vaccine to market, FUJIFILM hired many new employees who had little or no previous vaccine manufacturing experience, which was at least partly responsible for those delays. Likewise, as CW 1 explained, departments, such as

Operations, were focused on "wanting to push it out," referring to the vaccine, and asked the Regulatory Affairs department: "'What can we do to get done faster?'" CW 1—who worked as a Manager, Regulatory Affairs CMC at Novavax and helped manage manufacturing sites contracted by Novavax to produce its Covid-19 vaccine—was surprised by the Company's goal of producing two billion doses annually by mid-2021, and further expressed skepticism that Novavax would be able to do that, explaining that Novavax would have had to partner with everyone—meaning everyone in the biomedical manufacturing industry—if it were to meet that goal.

91. Additionally, the rush to develop and manufacture NVX-CoV2373 led Novavax to cut corners, which along with inadequate planning caused further delays. As CW 4 stated, "Novavax being small themselves and having to grow very quickly, I don't know if they were very prepared for this." CW 4 elaborated, recalling that when CW 4 arrived at Novavax, the Company kept a table or spreadsheet showing the various "lots" of the vaccine that were available, "what we can provide" for trials, and "what we have left." But CW 4 explained that this table then "went away," and that "it just felt like studies were falling from the sky but with no plan behind it." CW 4 further recalled that Novavax did not have a "clinical development plan,"[11] which she explained is typically needed.

92. Moreover, CW 8 recalled that, during her tenure, the vaccine was being produced under an accelerated timeline, and FUJIFILM would have to alter its processes "almost constantly." For example, CW 8 explained that because of the speed of the process, the quality control team once had to send the test methods used to test the product back to the analytical development team in order to include additional details. CW 8 further explained that the lapses

[11] One definition of a Clinical Development Plan is the blueprint of the entire clinical research strategy of a drug, which defines the critical path for the clinical program including development assessment and decision points and the project resource (personnel and budget) estimates.

were the result of certain steps being skipped in favor of an accelerated production timeline. CW 8 added that early analysis steps were skipped or done concurrently rather than being done prior to the production phase.

(d) Novavax Experienced Supply Chain Disruptions

93. Additionally, Novavax's supply chain constraints created further delays in its attempt to file its EUA with the FDA. For example, CW 6 explained that supply chain issues, such as domestic supply constraints and difficulty obtaining certain materials, "were always a struggle." CW 6 further explained that the U.S. government helped to get Novavax and FUJIFILM supplies to produce the Covid-19 vaccine, but CW 6 reiterated that these supply chain issues were "an ongoing issue."

94. Similarly, CW 7—who worked at the North Carolina Facility as a Manager, Quality Assurance—explained that Novavax had difficulty procuring the components necessary to manufacture its Covid-19 vaccine, such as filters and resin used in the manufacturing process. CW 7 recalled that the supply chain issues impacted Novavax for the duration of its vaccine development.

95. CW 5 recalled that there were difficulties in acquiring the necessary number of different components used in the manufacturing process due to global supply chain issues, and CW 5 recalled this including a lack of blades that were used in the manufacturing process. Likewise, CW 3 explained that Novavax experienced delays in sourcing raw materials "that did slow down our work," and CW 3 further explained that the raw materials were "usually things [Novavax] needed from different companies to use their machines." Specifically, CW 3 recalled that "certain companies require special trays with gel inside them for us to run a purity check," and that "they were having difficulty sourcing those materials, which required Novavax "to make [the materials] ourselves or try different ones."

2. The FDA Confirmed and Corroborated that Novavax's Critical Manufacturing Facilities Experienced Major Manufacturing Problems

96. As a result of the numerous contamination events and manufacturing problems plaguing Novavax's vaccine development, the FDA soon got involved. In March and April 2021, the FDA conducted inspections of the Texas and North Carolina Facilities. The inspections reports and related correspondence sent to Novavax's manufacturing facilities detailed the significant manufacturing problems facing the Company at the time.

97. For example, on March 3, 2021, the FDA notified via telephone the Texas Facility's Vice President of Quality Operations, Jose Torres,[12] of an upcoming investigation. Then, on March 15, 2021, the FDA issued a formal Notice of Inspection to Gerry Farrell, the Chief Operating Officer of the Texas Facility. Indeed, the FDA inspected the Texas Facility from March 15, 2021 to March 19, 2021, to gather information with a focus on assessing whether Novavax had controls in place to ensure that manufacturing operations would not adversely impact the safety, purity, and potency of vaccines then under development.

98. At the conclusion of the investigation, the FDA conducted a meeting with the management of the Texas Facility, which included Mr. Farrell (who identified himself as the most responsible person on site), during which the FDA discussed certain "Items of Concern" that arose during the FDA investigation. These concerns involved a number of quality issues, including that the facility had "sub optimal quality operations." In response, Mr. Torres emailed the FDA on April 9, 2021, with responses to the FDA's verbal observations.

[12] Mr. Torres oversees the Quality Assurance, Quality Control, and Regulatory activities at the Texas Facility. Mr. Torres has four direct reports and reports to David Patterson, Senior Director of Global Quality. Others involved in the Quality Unit at the Texas Facility are: Patricia Flaherty, Director of QA Compliance; Matt Dixon, Director of QA Operations; Travis Sadowski, Director of QC; and Rawle Collins, who oversees Regulatory Affairs and eQMS.

99. On April 14, 2021, the FDA issued a formal 52-page investigation memo, detailing a litany of issues with the Texas Facility ("April 14 FDA Report").[13]

100. The FDA observed and reported many issues relating to the Texas Facility's inadequate quality control, contamination, and purity issues, including but not limited to the following:

(a) Contamination was discovered and not properly recorded and investigated, including microbial contamination that was discovered in January 2021.

(b) Failure to investigate, detect, and document appropriately a number of deviations, and that periodic review of deviation trending was not performed by the Quality Unit.

(c) Cleaning procedure for certain manufacturing areas was not always followed, including using disinfectants on surfaces in manufacturing areas that were not effective in inactivating or adequately removing microorganisms.

(d) Failure to open "change controls" when appropriate. The report explained that the Change Control process "applies to all changes that may have the potential to impact product safety, quality, identity, purity, and strength at the [Texas Facility]."

(e) Out-of-specification ("OOS") investigation procedures were not always followed.

(f) Warehouse areas used for storage of GMP materials were overcrowded and poorly organized.

(g) Inadequate and ineffective training of manufacturing workers due to sharp increase in new hires.

101. The FDA again concluded: "***Quality oversight over manufacturing and testing operations is sub-optimal***."

[13] Notably, the FDA explained that it reviewed the Texas Facility's quality agreements in place at the time, and that "Fujifilm is required to notify the client of deviations and OOS results within 2 business days per section 12.0.1 of the agreements." Although the report redacted the name of the company with whom the Texas Facility entered into the quality agreements, according to the Head of Technical Operations at the Texas Facility, CW 5, the term "client" in this case was referring to Novavax. In fact, with respect to issues of contamination, CW 5 stated that a client, who was Novavax in this case, must be notified about a contamination within 24 to 48 hours of its discovery.

102. According to the April 14 FDA Report, Mr. Dixon "noted that it was challenging for the Quality Unit to keep up with review activities given the recent increase in work volume due to the rapid pace of product development," to which the FDA expressed "concerns regarding [the Texas Facility]'s ability to meet demand." Mr. Dixon further explained that failure to investigate deviations was caused by the "high throughput production." The FDA was thus further concerned about how the Quality Unit can assure product quality and safety while the manufacturing activities continue without timely closure of deviations.[14]

103. The FDA similarly found a number of problems during its investigation of the North Carolina Facility from April 14, 2021 to April 21, 2021. According to an FDA Form 483 issued to the North Carolina Facility on April 21, 2021 ("April 21 FDA Form 483"), the facility contained many quality-related problems, among others. For example, the April 21 FDA Form 483 observed and reported the following deviations at the North Carolina Facility:

(a) Microbial control of the facility was inadequate. Specifically, the facility's employees failed to investigate root causes and implement adequate corrective and preventative actions to control microbial contamination, as exemplified by the FDA learning from prior reports that microbial contamination (such as Paenibacillus spp., Burkholderia, Paenibacillus glucanolyticus, Penicillium rubens, and Fusarium oxysporum) was recovered from over 50 monitoring sites—including in purification sites.

(b) There was no comprehensive risk assessment conducted to evaluate cross-contamination of drug products, including where such drug products were manufactured in the same areas with shared product contact equipment.

[14] Relatedly, the FDA generated a memorandum on April 28, 2021, relating to the same investigation into the Texas Facility. The FDA explained that the purpose of the memorandum was to describe coverage completed as part of the pre-EUA investigation from March 15, 2021 to March 19, 2021, as it related to a complaint that was delivered to FDA investigator Scott Ballard's desk in the FDA Dallas district office on April 20, 2021. Specifically, the complaint that the FDA received outlined a number of issues that the FDA had also raised during the EUA investigation, which included the facility's lack of quality unit trending of deviations, failure to timely resolve and address deviations, failure to follow cleaning procedures, and others.

(c) The manufacturing process was not adequately monitored and/or controlled to ensure the quality of the drug substance was not adversely affected.

(d) Written procedures for manufacturing processes were inadequate, including inadequate procedures for the "Purification" step.

(e) Discrepancies were not fully investigated to identify a root cause and corrective and preventative actions were not adequately implemented to prevent recurrence.

(f) Procedures of material management systems were not followed or were inadequate, which led to expired materials being found in the warehouse.

104. In addition, former Novavax employees recalled that the FDA raised similar concerns during the Class Period. For example, CW 1 recalled that in response to the Module 3 reports submitted by Novavax (which, as explained below, contained information from the Company's manufacturing sites), the FDA raised concerns about the stability of the Company's vaccine batches. CW 1 said that the FDA communicated its concerns via information requests that were typically sent via email to Director – Regulatory Affairs Kathleen Callahan. Further, CW 1 explained that there was an inconsistency in not being able to repeat the result on a consistent basis, causing delays with respect to filing for EUA.

105. In fact, CW 1 recounted that she saw the end reports the FDA sent to the Company and knew from the reports that the stability of the vaccine batches Novavax had submitted "wasn't going to cut it" for the FDA. CW 1 also recalled that the FDA wanted to better understand a discrepancy in Novavax's potency levels, which were at 130% at one point and then at 120% another week.

106. CW 1 explained that she learned about the FDA's response and its concerns over the stability of Novavax's vaccine batches during weekly meetings with the Company's Regulatory Affairs team, and that the information was shared directly by Callahan. CW 1 recalled that the Regulatory Affairs team meetings were attended by Senior Director—Regulatory Affairs

CMC Jannine Haberman Cobb and a handful of other Regulatory Affairs employees. CW 1 said that Callahan attended the meetings at least once a week and at times would be pulled into daily meetings if the team felt it needed her guidance. CW 1 further stated that for a few months, the Regulatory Affairs team had to meet daily to keep up with the "overbearing" amount of documents that needed to be prepared for the FDA.

3. Defendants Knew About the Manufacturing Problems

(a) Defendants Stayed Apprised of the Manufacturing Problems, as Was Required by FDA Regulations

107. As explained above, cGMP regulations—to which Novavax was required to adhere—provide that Novavax's quality control unit "shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company." 21 C.F.R. § 211.22(a). Additionally, with respect to any "reports of inspectional observations issued by the [FDA], or any regulatory actions relating to good manufacturing practices brought by the [FDA]," or any investigations into complaints involving the "possible failure of a drug product to meet any of its specifications," cGMP regulations provide that Novavax be notified in writing about such issues. 21 C.F.R. § 211.180(f), § 211.198(a). This is the case even if Novavax was "not personally involved in or immediately aware of such actions." 21 C.F.R. § 211.180(f). Moreover, cGMP regulations require companies to maintain laboratory records, including information relating to "results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194(a)(6).

108. The FDA's very own reports explained that it reviewed the Texas Facility's quality agreements in place at the time, and that "Fujifilm is required to notify the client of deviations and OOS results within 2 business days per section 12.0.1 of the agreements." Notably, former

employees from the Texas Facility and North Carolina Facility confirm and corroborate that Novavax was notified about the manufacturing problems, such as poor purity results and contamination problems, that occurred throughout the Class Period. For example, according to CW 5, Novavax had two Onsite Employees at the Texas Facility, whom CW 5 identified as Technology Transfer Engineer Patrick Hash and Contractor Elizabeth Wang. Indeed, CW 5 explained that CW 5 and the Texas Facility Director of Manufacturing CW 6 communicated with the two Novavax's Onsite Employees "every single day" regarding manufacturing and the results of quality checks, which CW 5 recalled were conducted every 24 to 48 hours.

109. CW 5 recalled that Novavax's Onsite Employees were notified about each contamination issue that occurred throughout the Class Period. That is, they were notified about the four contamination incidents that led to delays in manufacturing that occurred since December 2020. CW 5 even recalled that Mr. Hash, one of Novavax's Onsite Employees, was involved in the investigations into the contaminations. CW 5 recalled that there were phone calls and emails about contaminations and delays from Mr. Hash to Novavax headquarters, including Novavax's Quality Assurance department.

110. CW 6 similarly recalled that Novavax had employees that worked onsite at the Texas Facility, including Mr. Hash, along with a few other Novavax employees who rotated onsite "off-and-on." CW 6 further recalled that CW 6 participated on Zoom calls "every day" with Novavax's Onsite Employees, a Novavax employee at Novavax's headquarters in Maryland named Ivailo, and other Novavax employees from different departments. According to CW 6, Novavax's Onsite Employees, Ivailo, as well as other Novavax employees "knew everything that we were doing." CW 6 further advised that there were typically 10 Novavax employees on these calls.

111. Similarly, CW 7—a former Manager, Quality Assurance for the North Carolina Facility—recalled that any issues were constantly communicated to Novavax, which had someone onsite at the North Carolina Facility weekly at a minimum. CW 7 advised that the level of Novavax's involvement was unlike anything she had previously encountered at FUJIFILM, meaning that Novavax was more involved in the manufacturing process than other clients at FUJIFILM.

112. CW 7 further explained that all testing results of batches at the North Carolina Facility were communicated to Novavax through a "batch record," which relayed to Novavax that testing was completed and the results of the testing. CW 7 even explained that FUJIFILM sometimes changed the vaccine manufacturing materials given certain supply chain issues, and that Novavax would have to approve all the changes. CW 7 recalled that Novavax had teams of people from departments including quality and technical who were involved in any modifications. CW 7 further explained that Novavax was involved with "everything" and was "driving" the way in which FUJIFILM manufactured the product. In fact, CW 7 advised that the level of Novavax's involvement was unlike anything she had previously encountered at FUJIFILM.

113. Further, CW 7 recounted that the vaccine's purity levels were manufactured according to information provided by and processes approved by Novavax. Additionally, CW 1 explained that FDA concerns were also discussed at weekly, and sometimes daily, Regulatory Affairs team meetings.

114. Furthermore, as mentioned above, Novavax was apprised by the FDA and Novavax's manufacturing partners at the Texas Facility and the North Carolina Facility of the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain that occurred at its facilities, including those of its partners such as FUJIFILM. In fact, according

to the October 19, 2021 *Politico* article referenced earlier, senior Trump administration officials on Operation Warp Speed repeatedly warned the Company that it risked running into problems in scaling up manufacturing of NVX-CoV2373. Specifically, these officials worried that Novavax would have difficulty ensuring that NVX-CoV2373 consistently met the FDA's rigorous quality standards once the vaccine went into mass production.

(b) Defendant Erck Personally Held Company-Wide Meetings Regarding NVX-CoV2373

115. Multiple former Novavax employees confirm that Defendant Erck held company-wide meetings with its employees where NVX-CoV2373 was discussed. For example, CW 2 recalled that Defendant Erck and Novavax's leadership team spoke to employees and facilitated Q&A sessions during Company-wide meetings that happened at least once a quarter; CW 2 explained that she, like most employees, attended the meetings virtually. At these meetings, CW 2 recalled that Defendant Erck discussed the topic of seeking regulatory approval.

116. Likewise, CW 1 recalled that Defendant Erck spoke to employees during monthly Company-wide meetings that included Q&A sessions, with employees being able to submit questions in advance via an app. CW 1 further recalled that the Q&A sessions included discussions about employees' concerns in regard to "our manufacturing capabilities" and "the likelihood of being able to manage all those stakeholders," in addition to concerns over whether Novavax would "be able to get our stability information stabilized."

(c) Internal Novavax Reports and Emails Contained Information from Manufacturing Facilities and Clinical Testing Updates

117. Furthermore, Defendant Erck had access to reports that contained hundreds of pages of data from Novavax's manufacturing sites. For example, CW 1 explained that Novavax submitted documents containing information from the Company's manufacturing sites that was then submitted to the FDA in the form of Module 3 Quality reports. CW 1 further explained that

"those are the documents we were working on the hardest," and that "Novavax really needed to have [its] CMC module in line before we could get that emergency use authorization." CW 1 recalled that these reports consisted of "hundreds of pages."

118. CW 1 explained that the content from the manufacturing sites that was detailed in the Module 3 reports involved drug and product information and data. CW 1 further explained that the Module 3 reports were submitted to the FDA via the agency's Electronic Submissions Gateway ("ESG") and sometimes via email, depending on the preferences of the two or three FDA project managers with whom Novavax worked. CW 1 recalled that Director – Regulatory Affairs Kathleen Callahan would send such emails and handled all communications with the FDA.

E. Defendants Reassure Investors That NVX-CoV2373 Was Aligned with FDA Criteria and Would Be Timely Filing Its EUA with the FDA

119. As described above, Novavax experienced a litany of manufacturing problems during the Class Period, such as not being able to achieve the required purity and potency levels as part of the FDA criteria, experiencing rampant contamination, failing to scale up production, and facing supply chain issues. Nonetheless, Defendants concealed these problems from investors and brazenly touted that Novavax was aligned with FDA criteria and had resolved any issues that could affect its ability to file its EUA.

120. On February 24, 2021, the first day of the Class Period, Defendant Glenn participated in an interview with *The Washington Post* to discuss Novavax's regulatory timeline for its EUA and Novavax's progress thus far to meet FDA requirements. To that end, Defendant Glenn touted that "we lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and ***so we're aligned up with those success criteria in all of our trials***."

121. However, contrary to Defendant Glenn's representation, Novavax at the time was in fact not able to meet the required purity and potency levels, which are criteria that the FDA required Novavax to meet to file its EUA and ultimately receive approval to bring NVX-CoV2373 to market. But this, of course, was something Defendants would not want to, and did not, tell investors at the time. Indeed, NVX-CoV2373 was critical to Novavax's success, and had Defendants disclosed the truth, it would have seriously jeopardized Novavax's stock price and future as a Company. To be sure, even analysts recognized how important NVX-CoV2373 was to Novavax. For example, as one analyst, Zacks, reported, "[a]ny delay in the study outcome or any developmental setback for . . . the COVID-19 vaccine candidate will be a major disappointment for the [C]ompany, leaving an adverse impact on its shares."

122. At the same time Defendants made their above statements concerning NVX-CoV2373, analysts were encouraged by Novavax's purported ability to meet FDA criteria and bring NVX-CoV2373 to market. Jefferies was encouraged that "[a]ltogether, everything remains on track, including EUA filing in UK, EU and USA in Q2." Similarly, Zacks noted that the "vaccine is also advancing well."

123. In fact, one analyst, CFRA, even issued a Strong Buy rating for Novavax and reported that "[w]e think 2021 could be a turnaround year for [Novavax]," and that "[w]e think [Novavax's] Covid-19 vaccine candidate is well-placed to receive the fourth EUA in the U.S. in Q2."

F. Defendants Delay the EUA Filings, Partially Revealing the Underlying Challenges They Faced—but Continue to Reassure Investors

124. Notwithstanding the litany of above-mentioned manufacturing problems that existed but were unknown to the public—and more importantly, right before Novavax announced news certain to drive the stock price down—some of the Individual Defendants chose that time to

financially enrich themselves before the inevitable news to be announced. Indeed, in mid-to-late April 2021, Defendant Glenn sold over 8,000 shares of Novavax stock and made over $1.6 million in proceeds before the devasting news to come.[15] Similarly, Defendant Trizzino sold over 3,000 shares of Novavax stock on May 5 and May 7, 2021, making nearly $600,000 in proceeds—as compared to the zero stock sales that he made in May of the previous year.[16]

125. Furthermore, in light of the manufacturing problems—which Defendants concealed from the public—Novavax was unable to stick to its regulatory timeline to file its EUA. Indeed, while Defendants had thus far been successful at keeping investors in the dark about Novavax's problems, Defendants were not able to conceal the regulatory delays that were caused by such problems. The fact of the matter is that Novavax was not able to file its EUA until it aligned its vaccine with the FDA's cGMP requirements. Because in reality Defendants were unable to meet such standards, Novavax was forced to delay its EUA filing.

126. Specifically, on May 10, 2021, during market hours, *The Washington Post* reported that Novavax's EUA "filing was delayed by manufacturing regulatory issues, until June at the earliest, according to four people who had recently been briefed on the [C]ompany's plans." Similarly, later that day, during after-market hours, on a call that Novavax hosted with investors and analysts to discuss the Company's first quarter 2021 financial and operational results (the "1Q21 Earnings Call"), Novavax confirmed that it was unlikely to seek an EUA for NVX-CoV2373 in the U.S. until July 2021 at the earliest—*i.e.*, the third quarter of 2021.

127. As a result, the price of Novavax common stock fell 8.81% on May 10, 2021, and, following the Company's 1Q21 Earnings Call, continued to fall an additional 13.91% on May 11,

[15] *See* SEC Form 4 of Gregory M. Glenn, dated April 19, 2021.
[16] *See* SEC Form 4 of John Trizzino, dated May 7, 2021.

2021. This news also elicited some concern from the market, which directly linked the drop to the delay. For example, Jefferies stated that "[s]hares of [Novavax] are taking a hit following the Q1 update." Zacks similarly reported, "Novavax announced that it[s] plans to file for authorization for Novavax in the United States . . . in the second quarter of 2021 have been delayed to the third quarter. The stock tanked on this news."

128. Yet, despite delaying its regulatory filing in light of the underlying, undisclosed manufacturing challenges, Defendants continued to reassure investors that the (non-public-but-lingering) causes of these regulatory delays were no longer an issue for Novavax. For example, on May 10, 2021, the same day that Defendants pushed out the regulatory timeline, Defendant Erck stated during the 1Q21 Earnings Call: "Our timetable for regulatory filings, we know that we're delayed from where we thought we'd be at this point. But now we're giving guidance that ***nearly all of the major challenges have been overcome*** and we can clearly see the light at the end of the tunnel."

129. During that same 1Q21 Earnings Call, an analyst from B. Riley Securities focused on Novavax's delayed submission and the reasons for its holdup. That analyst asked Defendant Erck if he was "able to comment on what might be these sort of things that are ***causing the holdup***," and whether "it [is] just process coordinating between the different sites" or "are there ***any specific issues*** around any particular assay." In response, while Defendant Erck stated that "part of it has to do with ***manufacturing at different sites*** and showing comparability between the processes and the actual end product between the different sites" and that "it probably took a little longer than we expected to get a potency assay that was worked across," Defendant Erck reassured the analyst that such issues were solved and behind Novavax. Specifically, Defendant Erck explained: "***I'm happy to say we did. We've crossed that bridge. We're – we made a big***

breakthrough ***there*** and we're now racing towards validating everything and putting it into a package."

130. Defendant Erck further assured investors that Novavax was past all of the hurdles causing delays in EUA approval: "[E]very quarter gets more data pointing to a successful vaccine, we're getting close to the end, and—which is really the beginning for us and that's what we're all racing to do. I think ***we've eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine***."

131. During that same 1Q21 Earnings Call, with respect to Novavax's "current state of [] manufacturing and [] anticipated capacity," Defendant Erck stated "I think we've done a remarkable job of standing up manufacturing in these multiple plants across the globe. ***I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants***. The drug substance production is the most complicated step in the overall manufacturing processes."

132. That is, Defendant Erck reassured investors that Novavax's manufacturing facilities were manufacturing NVX-CoV2373 to FDA standards—for which Novavax was directly responsible and in which it was involved.

133. Given the importance of Novavax's potential vaccine to the general public, on June 10, 2021, Novavax hosted Maryland Governor Larry Hogan at the site of the Company's planned Vaccines Innovation Campus and global headquarters in Gaithersburg. Additional guests included state, regional, and local officials. Defendants Erck and Glenn personally led the tour, providing an overview of the facility and press briefing.

134. On June 14, 2021, a few days later, Novavax participated in a Clinical Update call with investors. On that call, Defendant Erck again reassured investors that "[w]ith each analysis,

our trials proved that we are on the right track. And today, with safety and efficacy that are consistent across all studies, our PREVENT-19 results reaffirm our strong belief in [NVX-CoV2373]." These reassurances, however, were not true.

135. Yet, Defendants had successfully alleviated any major concerns the market may have initially had since Novavax announced that it was delaying its EUA filing. Indeed, in light of Defendants' continued reassurances, Jefferies noted that Novavax's management "remains confident in their ability to execute" and that, "[w]hile [filings with the FDA] took longer than they initially expected, it appears they have everything close to being set now." Cantor Fitzgerald also reported that despite Novavax's update, "according to management, facilities in its network have demonstrated the ability to manufacture commercial scale GMP material."

136. Similarly, H.C. Wainwright explained that "[w]e believe the [C]ompany remains a solid player in the COVID-19 vaccine landscape and think concerns about a delay in regulatory filings and manufacturing challenges are only temporary setbacks."

G. Rampant Contamination Issues Remained Unresolved and Worsened—Causing Manufacturing Processes to Shut Down

137. While the underlying manufacturing problems related to purity, potency, contamination, scalability, and the supply chain continued, CW 5 stated that the Texas Facility faced additional manufacturing problems concerning contamination starting in March 2021, and CW 6 similarly recalled contamination occurring since April 2021. Indeed, CW 5 recalled that in March 2021—around the same time Defendant Glenn sold a significant number of his shares—a viral contamination was discovered at the Texas Facility. CW 5 explained that some of the bacterial contaminations were traced back to newer employees who had no or little experience in vaccine manufacturing. CW 5 specifically recalled that the investigation revealed an "irido virus," which CW 5 explained was short for iridescent since the virus is iridescent under certain light.

CW 5 explained that the facility first identified the growth of the contamination on March 18, 2021, and let the run continue for two or three days before starting an investigation two or three days after that. CW 5 advised that the investigation ultimately concluded that the contamination was most likely due to human error. CW 6 similarly recalled that there was a contamination incident at the Texas Facility around sometime in April 2021.

138. Notably, CW 5 explained that the Texas Facility's manufacturing was shut down from March 2021 to at least September 2021—during which time Defendant Erck made massive stock sales. In fact, CW 5 confirmed that the facility was at a standstill when Novavax executives unloaded stock in July 2021. Likewise, CW 6 corroborated that the contamination incident in April 2021 led to a shutdown in manufacturing and further recalled that the resumption of manufacturing kept getting pushed back and that it had still not restarted by the time her tenure ended on June 30, 2021.

139. Additionally, CW 5 confirmed that every detail about this viral contamination was "communicated to" Novavax's Onsite Employees as the discovery and investigation progressed, along with daily calls with Novavax personnel in Maryland, where Novavax is headquartered. CW 5 added that a client, who was Novavax in this case, must be notified about a contamination within 24 to 48 hours of its discovery.

140. Similarly, CW 6 explained that CW 6 participated on Zoom calls "every day" with Novavax's Onsite Employees, a Novavax employee at Novavax's headquarters in Maryland named Ivailo, and other Novavax employees from different departments. According to CW 6, Novavax's Onsite Employees, Ivailo, and the other Novavax employees on the Zoom calls "knew everything that we were doing." CW 6 further advised that there were typically 10 Novavax employees on the calls.

141. Yet, instead of being upfront with investors about these issues, Defendants continued to conceal the truth. But not only that, as alluded to above, some of the Individual Defendants also went further and saw this as the opportune moment for them. Indeed, during July 2021—the very month that the Texas Facility was shut down and being investigated, as well as the litany of other issues still occurring—Defendant Erck sold over 100 thousand shares of Novavax stock, reaping proceeds of over $22.5 million.[17]

142. Similarly, Defendant Glenn also cashed in during this same time. For example, in July 2021, Defendant Glenn sold over 8,000 shares for proceeds of more than $1.5 million.[18]

H. Despite Novavax's Continued Manufacturing Problems Causing Additional Regulatory Filing Delays, Defendants Again Reassure Investors That Novavax No Longer Faces Such Issues

143. As with the previous quarter, Defendants were unable to prevent the inevitable risks from materializing as a result of the underlying manufacturing problems related to purity, potency, contamination, scalability, and the supply chain that Novavax was experiencing during the Class Period. As such, on August 5, 2021, Novavax further delayed its EUA filing and reported that it expected to file for NVX-CoV2373's EUA in the fourth quarter of 2021, rather than the third quarter of 2021.

144. On that same day, Novavax filed with the SEC its Form 10-Q for the quarter ending June 30, 2021 ("2Q21 Form 10-Q"), which was signed by Defendants Erck and Trizzino. The 2Q21 Form 10-Q revealed, "[t]he U.S. government has recently instructed the Company to prioritize alignment with the U.S. Food and Drug Administration on the Company's analytic

[17] *See* SEC Form 4 of Stanley Erck, dated July 6, 2021.

[18] *See* SEC Forms 4 of Gregory Glenn, dated July 19, 2021 and July 22, 2021.

methods before conducting additional U.S. manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made."

145. As a result, Novavax's stock price dropped 19.61% on August 6, 2021. Upon learning of this news, analysts were initially disappointed and shocked by the EUA filing delays. For example, Jefferies reported, "[w]e understand the lack of clarity around the US/EU filings is less than ideal." Notably, Seeking Alpha reported that the "news was a shocker for investors."

146. Conveniently, Defendants Erck and Glenn cashed in for tens of millions of dollars in stock sales proceeds in the weeks leading up to this announcement and prior to Novavax's stock losing almost 20% of its value.

147. Yet, despite having to push the regulatory timeline again, Defendants continued to conceal the full truth regarding the underlying problems Novavax faced. For example, according to an August 5, 2021 *Reuters* article about an interview between Defendant Erck and *Reuters*, Defendant Erck stated: "***We appear to have got past (certain) supply issues and are now being able to produce at scale***."

148. Additionally, on Defendants' August 5, 2021 conference call to discuss the earnings results for the second quarter of 2021 ("2Q21 Earnings Call"), Defendant Erck reassured investors that "[t]oday, we remain on track to achieve manufacturing capacity of 100 million doses per month by the end of the third quarter of '21 and 150 million doses per month by the end of the fourth quarter of '21."

149. Similarly, during that 2Q21 Earnings Call, an analyst from Jefferies asked Defendant Erck about "what gives you confidence that you'll be able to file in the U.S.," and "how much risk is there associated with addressing some of those last remaining issues that are the gating steps to those filings." In response, Defendant Erck stated that "the risk reduction is dramatic,"

and that "I think that it's a matter of now mechanics of getting all the data—final data assembled and submitted. And it's—we're talking weeks here. We're not talking months. So I'm not worried about the future submissions."

150. Additionally, the Jefferies analyst followed-up, asking: "So you believe that at least the time lines that you've put forth, you'll be able to reach those." In response, Defendant Erck again stated: "I do. This is a very big transformation – transition of the [C]ompany we filed. We've now filed with the regulatory agencies in 3 countries, and we've got a complete filing package for those we are finishing the additional requirements in the various countries that I mentioned. We've listed dates that we plan on making with a lot of confidence."

151. In fact, during that same 2Q21 Earnings Call, in response to a J.P. Morgan analyst's request for clarity on Defendants' disclosure about "the U.S. government saying that it would like to see FDA alignment on your analytical methods before conducting additional U.S. manufacturing," Defendant Erck downplayed the severity of the situation by explaining that "there's always a time lag with the FDA these days."

152. Additionally, to help further build investor confidence, Defendants also explained that they were regularly communicating with regulatory authorities and successfully incorporating such information into their work. For instance, during a September 21, 2021 conference at Devex UNGA 76, Defendant Trizzino stated that Defendants had "been in constant communication with [regulatory] authorities under rolling review and rolling submissions," and further explained that Defendants were "now at a point in time at which all of that feedback and all that conversation has been incorporated into these documents."

153. Notably, on September 29, 2021, during the Cantor Fitzgerald Global Healthcare Conference, Defendant Trizzino further reassured investors that certain manufacturing problems

were fixed. For example, in response to a Cantor Fitzgerald analyst's question about EUA and manufacturing, Defendant Trizzino said: "[T]he combination of our recombinant protein nanoparticle, its nanoparticle structure, the particle structure of our Matrix adjuvant presented some challenges in those assays, ***which have now been resolved***."

154. In light of Defendants' continued reassurances, analysts and the media remained optimistic. For example, despite finding that the delays were "less than ideal," Jefferies reported that "[m]anufacturing appears to be on track w[ith] the company reiterating plans to reach 100M doses/month and 150M doses/month by the end of Q3 and Q4, respectively." Similarly, Jefferies explained, "[w]hen asked what the gating steps are for submission to the UK/EU/US, [management] noted the need to reach each regulatory agencies' submission requirements, but the risk associated w[ith] these filings has been significantly reduced and [management] remains very confident they will be able to file." Additionally, Seeking Alpha stated that "[w]hile [Novavax] announced a delay in submission to US FDA, it is still on track to achieve its previously planned manufacturing capacity for Q3 and Q4."

155. However, contrary to the story that Defendants were selling investors, the manufacturing problems outlined above persisted—still preventing Novavax from achieving alignment with FDA criteria and filing its EUA. Again, this is largely due to Novavax rushing the process to meet the tight turnarounds required to obtain EUA approval before there was no longer a need. Indeed, as of September 29, 2021, the number of people in the United States with at least one Covid-19 dose exceeded 214 million people (compared to only 51,056,052 people at the start of the Class Period). Furthermore, while the Director of the Center for Biologics Evaluation and Research at the FDA, Peter Marks, was quoted by *Bloomberg* in the first week of August 2021 as saying that "right now, one wouldn't want to rule out continuing to give emergency use

authorizations," he also stated, "[t]here probably is going to be a point at which we stop[] giving emergency use authorizations." Defendants thus still felt the pressure to manufacture the Company's vaccine as quickly as possible—at all costs.

I. Investors Finally Learn About the Manufacturing Problems That Were Preventing Novavax from Filing Its EUA with the FDA

156. On October 19, 2021, *Politico* published an article, after market hours, entitled: "'They rushed the process': Vaccine maker's woes hamper global inoculation campaign," which revealed the manufacturing problems Novavax previously concealed. The *Politico* article—citing numerous Novavax employees with direct knowledge of and familiarity with Novavax's manufacturing process—revealed the underlying and undisclosed manufacturing problems that had been preventing Novavax from filing its EUA with the FDA and alerted investors for the first time that Novavax's timeline for approval was still ***another year away***.

157. Specifically, the article reported that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards" with respect to NVX-CoV2373. The article further explained that Novavax's "issues are more concerning than previously understood" and that the Company could ***take until the end of 2022 to resolve its manufacturing problems and win regulatory authorizations and approvals***.

158. Critically, the *Politico* article did not make references to just general manufacturing problems. Instead, the article detailed specific issues that were only internally known throughout the Class Period, such as the fact that Novavax had struggled to reach anywhere close to the purity levels required by the FDA. While the FDA sets a 90% purity level standard for each Covid-19 vaccine batch, the article revealed that Novavax had only recently shown purity levels hovering around 70%—still well below the 90% requirement. According to one person whom the article

quoted, "[a]t some level, I think the efficacy was never going to outweigh the risk associated with the impurity that was in there."

159. Similarly, according to the *Politico* article, the Company "has consistently run into production problems," including "[t]he methods it used to test the purity of the vaccine," which "have fallen short of regulators' standards" as Novavax "has not been able to prove that it can produce a shot that is consistently up to snuff, according to multiple people familiar with Novavax's difficulties."

160. As some U.S. government officials stated in the *Politico* article: "Novavax's manufacturing problems are seen as far more difficult to fix than the sanitary and design concerns that halted production of J&J's vaccine at the Emergent plant earlier this year."

161. Moreover, the *Politico* article also found that Novavax was already aware of specific concerns with NVX-CoV2373's manufacturing process, stating that "senior Trump administration officials on Operation Warp Speed . . . repeatedly warned the [C]ompany that it risked running into problems in scaling up manufacturing of the shot, two people with direct knowledge of those discussions said"; that, "[i]n particular, they worried that Novavax would have difficulty ensuring that the vaccine consistently met the FDA's rigorous quality standards once the vaccine went into mass production—the exact problem that has now stymied the [C]ompany for months"; and that Novavax "rushed the process" and "can't make" the vaccine, according to one of the people with knowledge of the matter.

162. As a result, the price of Novavax's stock fell 14.76% on October 20, 2021. Furthermore, *Politico* published another article the next day, on October 20, 2021, reporting that Novavax's issues were "worse than previously reported and could take several more months to set right." Analysts attributed the reason for the stock drop to the surprising news contained in the

Politico report. For example, Cantor Fitzgerald explained, "the recent news articles that cited 'anonymous sources' stating Novavax has manufacturing issues that are 'jeopardizing billions of doses earmarked for poor and middle-income countries' . . . has resulted in shares trading down today."

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

163. Lead Plaintiffs allege that the statements highlighted in bold and italics within this section were knowingly and materially false and misleading and/or omitted to disclose material information of which Defendants were aware or were reckless in not knowing. As alleged herein, such statements artificially inflated or maintained the price of Novavax's publicly traded common stock and operated as a fraud or deceit on all persons and entities that purchased common stock during the Class Period.

164. Throughout the Class Period, Defendants made a series of misrepresentations concerning Novavax's manufacturing capabilities and alignment with FDA criteria needed before filing its EUA for NVX-CoV2373 with the FDA. Specifically, Defendants made material misstatements and omissions including: (i) Novavax being aligned with FDA criteria while concealing multiple manufacturing problems, which included consistently falling short of FDA standards such as required purity and potency levels, experiencing rampant contamination problems, failing to scale up production of its vaccine, and facing supply chain disruptions; and (ii) when Novavax ultimately had to delay its EUA filing, reassuring investors that Novavax resolved such manufacturing problems that caused the delay.

A. February 24, 2021 – *The Washington Post* Interview

165. On February 24, 2021, during market hours, *The Washington Post* published an article relating to an interview it conducted with Defendant Glenn about Novavax and NVX-CoV2373. During that interview, Defendant Glenn reassured investors that Novavax was meeting

the standards set forth by the FDA. For example, Defendant Glenn touted: "[W]e lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and ***so we're aligned up with those success criteria in all of our trials***."

166. Analysts were encouraged by Defendants' purported ability to meet FDA criteria and in bringing NVX-CoV2373 to market. For example, on March 15, 2021, Zacks noted that the "vaccine is also advancing well." On March 25, 2021, Jefferies was encouraged that "[a]ltogether, everything remains on track, including EUA filing in UK, EU and USA in Q2." Similarly, on April 15, 2021, CFRA issued a Strong Buy rating for Novavax and reported that "[w]e think 2021 could be a turnaround year for [Novavax]," and that "[w]e think [Novavax's] Covid-19 vaccine candidate is well-placed to receive the fourth EUA in the U.S. in Q2." And Zacks continued to believe that the "vaccine [was] also advancing well" on April 28, 2021.

167. Analysts also recognized how important NVX-CoV2373 was to Novavax. For example, CFRA reported on April 15, 2021, that "the main focus of the [C]ompany is on its NVX-CoV2373 vaccine candidate against Covid-19," and that "[w]e think the future financial success of [Novavax] and its ability to record a positive bottom-line result is highly dependent on successful approvals and rapid commercialization of its Covid-19 vaccine." Similarly, as Zacks reported on April 28, 2021, "[a]ny delay in the study outcome or any developmental setback for . . . the COVID-19 vaccine candidate will be a major disappointment for the [C]ompany, leaving an adverse impact on its shares."

168. Defendant Glenn's statement in his interview with *The Washington Post* was materially false and misleading because, at that time, Novavax was in reality not aligned with FDA criteria needed to successfully manufacture and produce NVX-CoV2373. For example, Novavax had to ensure that it could produce its vaccine in large quantities while maintaining certain purity

and potency levels and complying with cGMP. However, Novavax was unable to achieve such criteria, and in fact also experienced other manufacturing problems, such as contamination, that further prevented Novavax from meeting FDA criteria. Indeed, CWs and multiple other individuals familiar with Novavax's manufacturing difficulties confirm that, since the beginning of the Class Period, Novavax suffered from multiple manufacturing problems related to purity, potency, contamination, scalability, and the supply chain.

169. Specifically, Defendant Glenn's statement was false and misleading because (i) NVX-CoV2373 was unable to meet certain FDA quality standards, such as purity and potency requirements; (ii) Novavax experienced rampant contamination; (iii) Novavax was unable to successfully scale up production; and (iv) Novavax's manufacturing process experienced supply chain disruptions.

170. For example, CWs, the FDA, and others familiar with Novavax's issues recalled that since the beginning of the Class Period, Novavax was not only unable to meet certain FDA quality standards needed to file its EUA, but also experienced multiple cGMP violations:

(a) Novavax had shown purity levels hovering around 70%—with some batches of vaccines containing purity levels of as low as 30%—which were nowhere close to reaching the 90% purity level generally understood to be required by FDA standards;

(b) Novavax was unable to reproduce a high-quality vaccine on a consistent basis, which was related to delays in filing for EUA;

(c) Novavax was unable to maintain the proper level of potency throughout 2021, which was a concern to the FDA and further delayed the regulatory process; and

(d) Module 3 reports submitted by Novavax to the FDA indicated that the stability of the vaccine batches "wasn't going to cut it" for the FDA.

171. Multiple CWs and the FDA likewise recounted that Novavax experienced rampant contamination problems that caused further delays:

(a) Microbial contamination was rampant in the Texas Facility—which, Defendants explained, was "a critical component of our US supply chain"—since December 2020;

(b) At least four contamination incidents occurred at the Texas Facility that led to delays in manufacturing that started between December 2020 and April 2021;

(c) Each contamination incident at the Texas Facility required shutting down development and interviewing the staff involved in the manufacturing process, which further delayed the manufacturing process;

(d) Contamination was discovered and not properly recorded and investigated in the Texas Facility, including microbial contamination that was discovered in January 2021; and

(e) Contamination existed in the North Carolina Facility throughout the entire Class Period, which required FUJIFILM to discard the batch, ending the process before they were able to test for purity (in the downstream) and resulting in lost batches of the vaccine.

172. Moreover, CWs also confirm Novavax's inability to scale up production throughout the Class Period:

(a) Novavax was not able to produce the required number of doses in time as Novavax was experiencing a shortage of vaccine doses for clinical trials, which were causing trials to be delayed;

(b) Novavax was not efficient at producing vaccines at a scale that would be needed for mass production; and

(c) Due to rushing the process, Novavax became disorganized and did not have a clinical development plan, which was something that is typically needed, and no longer kept a table or spreadsheet showing the various lots of the vaccine that were available, able to be provided for trials, and what was left, as Novavax had in the past.

173. Furthermore, CWs also recalled that Novavax was experiencing supply chain disruptions throughout the Class Period, which contributed to manufacturing and regulatory delays and Novavax's inability to scale up production and achieve alignment with FDA criteria:

(a) Supply chain issues—such as domestic supply constraints—at the Texas Facility "were always a struggle," and these supply chain issues and domestic supply constraints were "an ongoing issue";

(b) The North Carolina Facility had difficulty getting the components necessary to manufacture its Covid-19 vaccine, such as rubber silicone hoses and raw materials, which impacted Novavax for the duration of its vaccine development and caused Novavax to repeatedly delay its filing for EUA with the FDA;

(c) There were difficulties in acquiring the necessary number of different components used in the manufacturing process due to global supply chain issues, including a lack of blades that were used in the manufacturing process; and

(d) Novavax experienced delays in sourcing raw materials needed for purity tests, which slowed down Novavax's work.

B. May 10, 2021 – 1Q21 Earnings Call and Partial Disclosure / Materialization of the Risk

174. On May 10, 2021, for the first time, it was partially revealed that Novavax was experiencing manufacturing problems that were serious enough to prevent filing its EUA on the date Defendants previously promised. Specifically, on May 10, 2021, during market hours, *The Washington Post* reported that Novavax's EUA "filing was delayed by manufacturing regulatory issues, until June at the earliest, according to four people who had recently been briefed on the [C]ompany's plans." Similarly, later that day, after-market hours, during a conference call Novavax held to discuss the earnings results for the first quarter of 2021 ("1Q21 Earnings Call"), Novavax confirmed that it was unlikely to seek an EUA for NVX-CoV2373 in the United States until July 2021 at the earliest—*i.e.*, the third quarter of 2021.

175. In response, Novavax's stock price fell $15.50 per share, or 8.81%, to close at $160.50 per share on May 10, 2021. Moreover, following the Company's 1Q21 Earnings Call, Novavax's stock price continued to fall an additional $22.32 per share, or 13.91%, to close at $138.18 per share on May 11, 2021.

176. Analysts were initially disappointed by the news. For example, on May 11, 2021, CFRA reduced its rating on Novavax from Strong Buy to Buy in response to the news. Indeed, as Jefferies reported on May 11, 2021: "Shares of [Novavax] are taking a hit following the Q1 update." Similarly, on May 12, 2021, Zacks lowered its recommendation from neutral to underperform and stated: "Delay in the authorization filing for NVX-CoV2373, hurt the stock severely. Such delays in vaccine development do not bode well." Zacks specifically linked the delay to the stock drop: "Novavax announced that it[s] plans to file for authorization for Novavax in the United States, United Kingdom and the EU in the second quarter of 2021 have been delayed to the third quarter. The stock tanked on this news."

177. However, the Company's stock price remained artificially inflated after this announcement as Defendants knew but failed to disclose or deliberately disregarded the severity of the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain and Novavax's inability to achieve anywhere close to the FDA criteria needed to file its EUA. Instead, Defendant Erck reassured investors that any issues that Novavax may have experienced were behind Novavax, and continued convincing investors Novavax was on track to filing its EUA.

178. For example, on that same day, May 10, 2021, during the 1Q21 Earnings Call, Defendant Erck touted that the regulatory and manufacturing hurdles causing the delay were now resolved: "Our timetable for regulatory filings, we know that we're delayed from where we thought we'd be at this point. But now we're giving guidance that ***nearly all of the major challenges have been overcome*** and we can clearly see the light at the end of the tunnel."

179. During that same 1Q21 Earnings Call, an analyst from B. Riley Securities asked, with respect to Novavax's delayed submission: "[A]re you able to comment on what might be

these sort of things that are causing the holdup? Is it just process coordinating between the different sites? Or are there any specific issues around any particular assay?" In response, Defendant Erck reassured investors that the Company had fixed the issues that caused the delays: "No. I mean, and part of it has to do with manufacturing at different sites and showing comparability between the processes and the actual end product between the different sites. And you have to develop assays that can follow those. And so I think it probably took a little longer than we expected to get a potency assay that was worked across – told the same story across all the sites. ***But I'm happy to say we did. We've crossed that bridge. We're – we made a big breakthrough there and we're now racing towards validating everything and putting it into a package***."

180. During that same 1Q21 Earnings Call, with respect to Novavax's "current state of [] manufacturing and [] anticipated capacity," Defendant Erck stated: "Today, our global supply chain now spans over 10 countries ***with all of our manufacturing sites producing GMP material at scale***. I think we've done a remarkable job of standing up manufacturing in these multiple plants across the globe. ***I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants***. The drug substance production is the most complicated step in the overall manufacturing processes."

181. During that 1Q21 Earnings Call, Defendant Erck further assured investors that Novavax was past all of the hurdles causing delays in EUA approval: "[E]very quarter gets more data pointing to a successful vaccine, we're getting close to the end, and – which is really the beginning for us and that's what we're all racing to do. I think ***we've eliminated all of the serious hurdles to getting – risk hurdles to getting to where we need to be to get an improved vaccine***."

182. Analysts believed Defendants' story that such issues had been resolved and were encouraged by Defendants' reassurances. For example, on May 10, 2021, Jefferies reported that Novavax's "[management] remains very confident that they will hit 150M doses per month before the end of the year and expects to maintain that throughout 2022 and beyond." Jefferies similarly reported that Novavax's management "remains confident in their ability to execute" and that, "[w]hile [filings with the FDA] took longer than they initially expected, it appears they have everything close to being set now."

183. Likewise, on May 11, 2021, Jefferies reported, "[w]hile the delays are clearly disappointing, we remain constructive on the name and see the outlook as promising given the clear high efficacy, clean safety profile, robust data package and optionality for a multivalent and/or CV-19/Flu combo vaccine." Cantor Fitzgerald also reported on May 11, 2021, that despite Novavax's update, "according to management, facilities in its network have demonstrated the ability to manufacture commercial scale GMP material." Similarly, on May 12, 2021, H.C. Wainwright reported: "We believe the [C]ompany remains a solid player in the COVID-19 vaccine landscape and think concerns about a delay in regulatory filings and manufacturing challenges are only temporary setbacks." H.C. Wainwright also reported: "We believe these challenges are temporary, as Novavax expects the remainder of capacity to come online and reach 150M doses per month in 4Q21, which is in line with the [C]ompany's stated goal of full capacity of 2B doses per year by [year end 2021]."

184. Defendant Erck's statements during the 1Q21 Earnings Call were materially false and misleading for the same reasons set forth in paragraphs 168–173 herein. In addition to those reasons, at the time Defendant Erck made these reassurances on May 10, 2021, the Texas Facility and North Carolina Facility experienced additional manufacturing problems. As noted, the FDA

conducted an inspection of the Texas Facility from March 15, 2021 to March 19, 2021, and the FDA issued on April 14, 2021 a formal 52-page investigation memo that detailed a litany of cGMP violations and manufacturing issues with the facility, which were reported to Novavax. The FDA ultimately concluded that "[q]uality oversight over manufacturing and testing operations is sub-optimal."

185. For example, the FDA found (i) evidence of contamination in the Texas Facility, which was not properly recorded and investigated; (ii) failure to investigate, detect, and document appropriately a number of other deviations; (iii) that periodic review of deviation trending was not performed by the Quality Unit; and (iv) that the cleaning procedure for certain manufacturing areas was not always followed, including using disinfectants on surfaces in manufacturing areas that were not effective in inactivating or adequately removing microorganisms.

186. Additionally, the FDA similarly found a number of issues during its investigation of the North Carolina Facility from April 14, 2021 to April 21, 2021—only weeks before Defendants' May 10, 2021 statements. According to the FDA, the investigation of the North Carolina Facility revealed many quality-related issues, including that: (i) microbial control of the facility was inadequate, which led to rampant contamination of the facility; (ii) there was no comprehensive risk assessment conducted to evaluate cross-contamination of drug products, including where such drug products were manufactured in the same areas with shared product contact equipment; (iii) written procedures for manufacturing processes were inadequate, including inadequate procedures for the "Purification" step; (iv) the manufacturing process was not adequately monitored and/or controlled to ensure the quality of the drug substance was not adversely affected; and (v) other discrepancies were not fully investigated to identify a root cause and corrective and preventative actions were not adequately implemented to prevent recurrence.

187. Specifically, the FDA found a failure to investigate root causes and implement adequate corrective and preventative actions to control microbial contamination, as exemplified by the FDA learning from prior reports that microbial contamination was recovered from over 50 monitoring sites.

188. Notably, as explained in Section IV.G, according to CW 5, at the Texas Facility, a more serious contamination incident involving an "irido virus" (*i.e.*, iridescent virus) contamination was discovered on March 18, 2021. CW 5 recalled that the facility let the run continue for two or three days before starting an investigation two or three days after that, and caused a shutdown in manufacturing from March 2021 until at least September 2021. Indeed, Director of Manufacturing at the Texas Facility, CW 6, corroborated that there was a contamination incident at the Texas Facility discovered in April 2021, which led to a manufacturing shutdown that had not restarted by the time her tenure ended on June 30, 2021.

189. Thus, Defendants' above May 10, 2021 statements—*e.g.*, "nearly all of the major challenges have been overcome," "we've successfully manufactured our drug substance . . . at commercial scale in each of these plants," "we've eliminated all of the serious hurdles to getting – risk hurdles to getting to where we need to be to get an improved vaccine," and similar misstatements—were materially false and misleading because Defendants had not yet overcome the manufacturing problems, including (a) not being able to meet the requisite purity and potency levels for NVX-CoV2373; (b) experiencing rampant contamination in critical manufacturing facilities; (c) failing to successfully scale up production; and (d) facing supply chain disruptions that existed since the start of the Class Period and continued throughout. Indeed, at the time of these misstatements, Novavax's critical manufacturing facilities faced serious cGMP violations,

such as rampant contamination issues, and were unable to achieve alignment with FDA criteria. These issues in turn caused further manufacturing and regulatory delays.

C. June 14, 2021 – Clinical Update Call

190. On June 14, 2021, during a Clinical Update Call on NVX-CoV2373, Defendant Erck reassured investors that "***[w]ith each analysis, our trials proved that we are on the right track. And today, with safety and efficacy that are consistent across all studies, our PREVENT-19 results reaffirm our strong belief in [NVX-CoV2373]***."

191. Analysts were again encouraged by Defendants' positive statements. For example, on June 14, 2021, Cantor Fitzgerald stated that "according to management, the eight facilities (up from zero a year ago) in its network have demonstrated the ability to manufacture commercial scale GMP material." Similarly, on the same day, Jefferies emphasized the importance of filing Novavax's data with regulatory agencies for approval and noted that Novavax said that it was on track to do so: "Key to [Novavax] will be [its] ability to execute on filing [its] data to the various regulatory agencies for EUA approval, ability to manufacture doses of [its] vaccine, and procure additional contracts. To these points, [management] reiterated Q3 timing on filings and achieving production goal of 100M dose/month by the end of Q3 and 150M dose/month by [year end]."

192. At this point in time, analysts were still encouraged by Novavax's ability to scale up production and meet cGMP standards. For instance, on August 4, 2021, Cantor Fitzgerald again reported that "according to management, the eight facilities (up from zero a year ago) in its network have demonstrated the ability to manufacture commercial scale GMP material."

193. Defendant Erck's statement during the Clinical Update Call was materially false and misleading for the same reasons set forth in paragraphs 168–173 and 184–189 herein. Indeed, at the same time Defendant Erck was claiming that "our trials proved that we are on the right track," Novavax was experiencing a shortage of vaccine doses for clinical trials, which were

causing trials to be delayed. Additionally, during this same time, Novavax was still experiencing the litany of manufacturing problems and delays outlined above. In fact, at this same time, manufacturing of NVX-CoV2373 at the Texas Facility was completely shut down.

D. August 5, 2021 – *Reuters* Interview and Partial Disclosure / Materialization of the Risk

194. On August 5, 2021, it was further partially revealed that Novavax was still experiencing manufacturing problems that affected Novavax's ability to file its EUA. Specifically, on August 5, 2021, Novavax further delayed its EUA filing and reported that it expected to file for NVX-CoV2373's EUA in the fourth quarter of 2021, rather than the third quarter of 2021. Additionally, Novavax's 2Q21 Form 10-Q further revealed that "[t]he U.S. government has recently instructed the Company to prioritize alignment with the U.S. Food and Drug Administration on the Company's analytic methods before conducting additional U.S. manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made."

195. In response, Novavax's stock price fell $46.31 per share, or 19.61%, to close at $189.89 per share on August 6, 2021.

196. Analysts and the media were initially disappointed and shocked by this news. For example, on August 6, 2021, Jefferies reported: "We understand the lack of clarity around the US/EU filings is less than ideal." Similarly, that same day J.P. Morgan reported: "With respect to filing timelines in the US, the US [government] has requested the completion of manufacturing validation activities prior to a regulatory submission, as such a US EUA filing is now anticipated in 4Q (3Q prior)." Similarly, on August 7, 2021, Seeking Alpha reported that the "news was a shocker for investors."

197. However, the Company's stock price remained artificially inflated after this announcement as Defendants knew and failed to disclose or deliberately disregarded the severity of the manufacturing problems, which included consistently falling short of FDA standards such as required purity and potency levels, experiencing rampant contamination problems, failing to scale up production of its vaccine, facing supply chain disruptions, and Novavax's inability to achieve anywhere close to the FDA criteria needed to file its EUA. Instead, Defendant Erck continued to lead investors to believe that Novavax's issues were resolved.

198. For example, according to an August 5, 2021 *Reuters* article that discussed an interview between Defendant Erck and *Reuters*, Defendant Erck stated: "***We appear to have got past (certain) supply issues and are now being able to produce at scale***."

199. Analysts and the media were encouraged by Defendants' reassurances as Defendants undoubtedly convinced the public that any such issues were resolved and would no longer cause challenges to Novavax. For example, despite finding that the delays were "less than ideal," Jefferies reported on August 5, 2021, that "[m]anufacturing appears to be on track w[ith] the [C]ompany reiterating plans to reach 100M doses/month and 150M doses/month by the end of Q3 and Q4, respectively." Similarly, the next day, on August 6, 2021, Jefferies explained, "[w]hen asked what the gating steps are for submission to the UK/EU/US, [management] noted the need to reach each regulatory agencies' submission requirements, but the risk associated w[ith] these filings has been significantly reduced and [management] remains very confident they will be able to file."

200. Also on August 6, 2021, Cantor Fitzgerald reported that, "[o]n the manufacturing front, the [C]ompany . . . remain[s] on track to achieve capacity of 100M doses per month by the end of 3Q21, and 150M doses per month by the end of 4Q21." Likewise, Seeking Alpha reported

on August 7, 2021, that "[w]hile [Novavax] announced a delay in submission to US FDA, it is still on track to achieve its previously planned manufacturing capacity for Q3 and Q4."

201. Defendant Erck's statement during his interview with *Reuters* was materially false and misleading for the same reasons set forth in paragraphs 168–173 and 184–189 herein. Indeed, at the time of Defendant Erck's reassurance, Novavax was still unable to scale up production and manufacturing problems, such as not being able to meet the requisite purity and potency levels for NVX-CoV2373, experiencing rampant contamination in critical manufacturing facilities, failing to successfully scale up production, and facing supply chain disruptions, continued to prevent Novavax from doing so.

E. September 21, 2021 – Devex UNGA 76 Conference

202. On September 21, 2021, Defendants attended a conference at Devex UNGA 76. During that conference, the Senior Global Health Reporter at Devex raised the topic of transparency on the part of manufacturers, such as Novavax. In response, Defendant Trizzino explained: "This transparency is important. ***And we've been extremely transparent across multiple fronts. All of our clinical data has been shared very quickly***."

203. Defendant Trizzino's statement during the Devex UNGA 76 Conference was materially false and misleading for the same reasons set forth in paragraphs 168–173 and 184–189 herein. Indeed, Defendant Trizzino's representation directly contradicts Defendants' conduct throughout the entire Class Period. Despite constantly discussing NVX-CoV2373's manufacturing process and development, Defendants had not been transparent with respect to the litany of manufacturing problems related to purity, potency, contamination, scalability, and the supply chain related to NVX-CoV2373 that persisted throughout the entire Class Period, let alone "extremely" transparent.

F. September 29, 2021 – Cantor Fitzgerald Global Healthcare Conference

204. On September 29, 2021, during the Cantor Fitzgerald Global Healthcare Conference, Defendant Trizzino reassured investors that manufacturing problems that had delayed Novavax's EUA filing were fixed. For example, in response to a Cantor Fitzgerald analyst's question about EUA and manufacturing, Defendant Trizzino touted: "[T]he combination of our recombinant protein nanoparticle, its nanoparticle structure, the particle structure of our Matrix adjuvant presented some challenges in those assays, ***which have now been resolved***."

205. Defendant Trizzino's statement during the Cantor Global Healthcare Conference was materially false and misleading for the same reasons set forth in paragraphs 168–173 and 184–189 herein. Indeed, even at this time, Defendants had still not resolved the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain that had prevented Novavax from meeting FDA criteria and filing its EUA.

G. October 19, 2021 – Final Disclosure / Materialization of the Risk

206. On October 19, 2021, the full truth concerning Novavax's underlying manufacturing problems was fully revealed and/or materialized. On that date, *Politico* published an article, after market hours, entitled: "'They rushed the process': Vaccine maker's woes hamper global inoculation campaign," which revealed the underlying and undisclosed manufacturing problems that had been preventing Novavax from filing its EUA with the FDA.

207. Specifically, the article reported that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards" with respect to NVX-CoV2373. The article further explained that Novavax's "issues are more concerning than previously understood" and that the Company could take until the end of 2022 to resolve its manufacturing issues and win regulatory authorizations and approvals.

208. Additionally, while the *Politico* article explained that the FDA generally sets a 90% purity level standard for each Covid-19 vaccine batch, the article revealed from reliable sources that Novavax had only recently shown purity levels hovering around 70%. According to one person whom the article quoted with knowledge of the matter: "At some level, I think the efficacy was never going to outweigh the risk associated with the impurity that was in there."

209. Similarly, according to the *Politico* article, the Company "has consistently run into production problems," including "[t]he methods it used to test the purity of the vaccine," which "have fallen short of regulators' standards" as Novavax "has not been able to prove that it can produce a shot that is consistently up to snuff, according to multiple people familiar with Novavax's difficulties." As some U.S. officials stated in the *Politico* article, "Novavax's manufacturing problems are seen as far more difficult to fix than the sanitary and design concerns that halted production of J&J's vaccine at the Emergent plant earlier this year."

210. Moreover, the *Politico* article also found that Novavax was already aware of specific concerns with NVX-CoV2373's manufacturing process, stating that "senior Trump administration officials on Operation Warp Speed . . . repeatedly warned the [C]ompany that it risked running into problems in scaling up manufacturing of the shot, two people with direct knowledge of those discussions said"; that, "[i]n particular, they worried that Novavax would have difficulty ensuring that the vaccine consistently met the FDA's rigorous quality standards once the vaccine went into mass production—the exact problem that has now stymied the [C]ompany for months"; and that Novavax "rushed the process" and "can't make" the vaccine, according to one of the people with knowledge of the matter.

211. In response, Novavax's stock price fell $23.69 per share, or 14.76%, to close at $136.86 per share on October 20, 2021. Additionally, *Politico* reported on October 20, 2021, that

Novavax's issues were "worse than previously reported and could take several more months to set right."

VI. LOSS CAUSATION

212. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Novavax common stock and operated as a fraud or deceit on Class Period purchasers of Novavax common stock by failing to disclose and misrepresenting the adverse facts detailed herein.

213. Class members unknowingly and in reliance upon Defendants' materially false or misleading statements and/or omissions purchased Novavax common stock at artificially inflated prices. But for Defendants' misrepresentations, omissions, and fraudulent scheme, Lead Plaintiffs and other Class members would not have purchased Novavax stock at the artificially inflated prices at which it traded during the Class Period.

214. The truth regarding Defendants' fraud was revealed in a series of partial corrective disclosures and/or materializations of concealed risk that occurred between May 10, 2021 and October 19, 2021. During this period, Novavax's stock fell precipitously as the artificial inflation caused by Defendants' unlawful conduct exited Novavax's stock price. It was not until the final partial corrective disclosure and/or materialization of concealed risk on October 19, 2021, that the full truth was known to the market, such that there was no longer any artificial inflation in Novavax's stock price attributable to the fraud.

215. The declines in Novavax's stock price during this period, including the declines summarized below, are directly attributable to the market absorbing information that corrected and/or reflected the materialization of risks concealed by Defendants' material misrepresentations or omissions.

216. As a result of their purchases of Novavax common stock during the Class Period, Lead Plaintiffs and the other Class members suffered economic loss (*i.e.*, damages) under the federal securities laws. Defendants' materially false and misleading statements had the intended effect and caused Novavax common stock to trade at artificially inflated levels throughout the Class Period.

217. By concealing from investors the adverse facts detailed herein, Defendants presented a misleading picture of Novavax's business. As the truth about the Company and the extent of the fraud was revealed to the market, the price of Novavax common stock fell significantly. These declines removed the inflation from the price of Novavax common stock, causing real economic loss to investors who had purchased Novavax common stock during the Class Period.

218. Each decline in the price of Novavax common stock, as detailed below, was a direct or proximate result of the nature and extent of Defendants' fraudulent misrepresentations and/or omissions being revealed to investors and the market.

219. The economic loss, *i.e.*, damages, suffered by Lead Plaintiffs and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Novavax common stock and the subsequent significant decline in the value of Novavax common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

220. The market for Novavax common stock was open, well-developed, and efficient at all relevant times, with average daily trading volume of approximately 4,299,450 shares during the Class Period. As a result of Defendants' misstatements and material omissions, as alleged herein, Novavax's common stock traded at artificially inflated prices. Lead Plaintiffs and other

Class members purchased Novavax common stock relying upon the integrity of the market relating to Novavax common stock and suffered economic losses as a result thereof.

221. The declines in Novavax's common stock price on May 10–11, 2021, August 6, 2021, and October 20, 2021, were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors during market hours on May 10, 2021, and after the market closed on August 5, 2021 and October 19, 2021. The timing and magnitude of Novavax's stock price declines evidence the impact Defendants' statements had on the Company's stock price during the Class Period and negate any inference that the loss suffered by Lead Plaintiffs and other Class members was caused by changed market conditions or macroeconomic, industry, or Company-specific factors unrelated to Defendants' fraudulent conduct.

A. May 10, 2021 – First Partial Disclosure / Materialization of the Risk

222. On May 10, 2021, the relevant truth and foreseeable risks concealed by Defendants' misconduct and their false representations and omissions during the Class Period were revealed and/or partially materialized when *The Washington Post* reported during market hours that Novavax's EUA "filing was delayed by manufacturing regulatory issues, until June at the earliest, according to four people who had recently been briefed on the [C]ompany's plans."

223. Later that day after market hours, during the 1Q21 Earnings Call, Novavax confirmed that it was unlikely to seek an EUA for NVX-CoV2373 in the U.S. until July 2021 at the earliest—*i.e.*, the third quarter of 2021.

224. The May 10, 2021 disclosures about Novavax delaying its EUA filing because of manufacturing regulatory issues were foreseeable consequences of, and within the zone of risk concealed by, Defendants' misrepresentations and omissions concerning Novavax's then-current

state of its manufacturing processes and capabilities and Novavax's purported alignment with FDA criteria.

225. Moreover, *The Washington Post* article and 1Q21 Earnings Call revealed new information that Defendants' misstatements, omissions, and fraudulent course of conduct previously concealed and/or obscured from the market. *The Washington Post* article and 1Q21 Earnings Call partially (but incompletely) revealed some of the relevant truth concealed and/or obscured by Defendants' prior misstatements and omissions surrounding Novavax's underlying manufacturing problems that were preventing Novavax from filing its EUA with the FDA.

226. As a direct and proximate result of this partial corrective disclosure and/or materialization of foreseeable risks concealed by Defendants' fraud, the price of Novavax common stock fell $15.50 per share, or 8.81%, to close at $160.50 per share on May 10, 2021. Moreover, following the Company's 1Q21 Earnings Call, Novavax's stock price continued to fall an additional $22.32 per share, or 13.91%, to close at $138.18 per share on May 11, 2021.

227. Upon learning of this news, analysts were initially disappointed. For example, on May 11, 2021, CFRA reduced its rating on Novavax from Strong Buy to Buy in response to the news. Indeed, as Jefferies reported on May 11, 2021, "[s]hares of [Novavax] are taking a hit following the Q1 update." Similarly, on May 12, 2021, Zacks lowered its recommendation from neutral to underperform and stated: "Delay in the authorization filing for NVX-CoV2373, hurt the stock severely. Such delays in vaccine development do not bode well." Zacks specifically linked the delay to the stock drop: "Novavax announced that it[s] plans to file for authorization for Novavax in the United States, United Kingdom and the EU in the second quarter of 2021 have been delayed to the third quarter. The stock tanked on this news."

228. Still, the Company's stock price remained artificially inflated even after this news, as Defendants continued to reassure the market that any manufacturing problems related to purity, potency, contamination, scalability, and the supply chain were resolved. For example, Defendant Erck reassured investors that "nearly all of the major challenges have been overcome and we can clearly see the light at the end of the tunnel."

229. Similarly, with respect to solving certain manufacturing problems that caused the EUA filing delay, Defendant Erck explained: "I'm happy to say we did. We've crossed that bridge. We're—we made a big breakthrough there and we're now racing towards validating everything and putting it into a package." Defendant Erck likewise told investors that "we've eliminated all of the serious hurdles to getting—risk hurdles to getting to where we need to be to get an improved vaccine."

230. Defendant Erck also stated that Novavax's then-current manufacturing progress of NVX-CoV2373 was doing so well that "[w]ith respect to the U.S. market, we are well positioned with our technology and timing to supply product for boosting and seasonal revaccination." Indeed, Defendant Erck touted that "all of our manufacturing sites [are] producing GMP material at scale," and that "I'm happy to report that we have got to the point where we've successfully manufactured our drug substance, a recombinant protein nanoparticle, at commercial scale in each of these plants."

231. Analysts were reassured that any manufacturing problems that Novavax experienced had been resolved and that Novavax no longer faced such challenges. For example, on May 10, 2021, Jefferies noted that Novavax's management "remains confident in their ability to execute" and that, "[w]hile [filings with the FDA] took longer than they initially expected, it appears they have everything close to being set now." Likewise, on May 11, 2021, Jefferies

reported: "While the delays are clearly disappointing, we remain constructive on the name and see the outlook as promising given the clear high efficacy, clean safety profile, robust data package and optionality for a multivalent and/or CV-19/Flu combo vaccine."

232. Cantor Fitzgerald also reported on May 11, 2021, that despite Novavax's update, "according to management, facilities in its network have demonstrated the ability to manufacture commercial scale GMP material."

233. Similarly, on May 12, 2021, H.C. Wainwright reported: "We believe the [C]ompany remains a solid player in the COVID-19 vaccine landscape and think concerns about a delay in regulatory filings and manufacturing challenges are only temporary setbacks." H.C. Wainwright also reported: "We believe these challenges are temporary, as Novavax expects the remainder of capacity to come online and reach 150M doses per month in 4Q21, which is in line with the [C]ompany's stated goal of full capacity of 2B doses per year by [year end 2021]."

B. August 5, 2021 – Second Partial Disclosure / Materialization of the Risk

234. On August 5, 2021, the relevant truth and foreseeable risks concealed by Defendants' misconduct and their false representations and omissions during the Class Period were further revealed and/or partially materialized when Novavax issued a press release reporting its financial results and operational highlights for the second quarter of 2021. Among other news, Novavax reported that it expected to file for NVX-CoV2373's EUA in the fourth quarter of 2021, rather than the third quarter of 2021.

235. On that same day, Novavax filed with the SEC its 2Q21 Form 10-Q, which was signed by Defendants Erck and Trizzino. The 2Q21 Form 10-Q further revealed, "[t]he U.S. government has recently instructed the Company to prioritize alignment with the U.S. Food and Drug Administration on the Company's analytic methods before conducting additional U.S.

manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made."

236. The August 5, 2021 disclosures about Novavax's additional regulatory filing delays and the FDA's instruction to Novavax to prioritize aligning its analytic methods with the FDA were foreseeable consequences of, and within the zone of risk concealed by, Defendants' misrepresentations and omissions concerning Novavax's then-current state of its manufacturing processes and capabilities and Novavax's purported alignment with FDA criteria.

237. Moreover, the August 5, 2021 press release and 2Q21 Form 10-Q revealed new information that Defendants' misstatements, omissions, and fraudulent course of conduct previously concealed and/or obscured from the market. The August 5, 2021 press release and 2Q21 Form 10-Q partially (but incompletely) revealed some of the relevant truth concealed and/or obscured by Defendants' prior misstatements and omissions surrounding Novavax's continued manufacturing problems that were still affecting Novavax's ability to file its EUA.

238. As a direct and proximate result of this partial corrective disclosure and/or materialization of foreseeable risks concealed by Defendants' fraud, the price of Novavax common stock fell $46.31 per share, or 19.61%, to close at $189.89 per share on August 6, 2021.

239. Analysts and the media were initially disappointed and shocked by this news. For example, on August 6, 2021, Jefferies reported, "[w]e understand the lack of clarity around the US/EU filings is less than ideal." Similarly, that same day J.P. Morgan reported, "[w]ith respect to filing timelines in the US, the US [government] has requested the completion of manufacturing validation activities prior to a regulatory submission, as such a US EUA filing is now anticipated in 4Q (3Q prior)."

240. Similarly, on August 7, 2021, Seeking Alpha reported that the "news was a shocker for investors."

241. Still, the Company's stock price remained artificially inflated even after this news, as Defendants continued to reassure the market that such manufacturing issues were resolved and that Novavax was on track to filing its EUA. For example, Defendant Erck reassured investors that "[w]e appear to have got past (certain) supply issues and are now being able to produce at scale."

242. Despite their initial disappointment, analysts and the media were encouraged by Defendants' reassurances as Defendants convinced the public that any such issues were resolved and would no longer cause challenges to Novavax. For example, despite finding that the delays were "less than ideal," Jefferies reported on August 5, 2021, that "[m]anufacturing appears to be on track w[ith] the company reiterating plans to reach 100M doses/month and 150M doses/month by the end of Q3 and Q4, respectively." Similarly, the next day, on August 6, 2021, Jefferies explained, "[w]hen asked what the gating steps are for submission to the UK/EU/US, [management] noted the need to reach each regulatory agencies' submission requirements, but the risk associated w[ith] these filings has been significantly reduced and [management] remains very confident they will be able to file."

243. Also on August 6, 2021, Cantor Fitzgerald reported that, "on the manufacturing front, the [C]ompany . . . remain[s] on track to achieve capacity of 100M doses per month by the end of 3Q21, and 150M doses per month by the end of 4Q21." Likewise, Seeking Alpha reported on August 7, 2021, that "[w]hile [Novavax] announced a delay in submission to US FDA, it is still on track to achieve its previously planned manufacturing capacity for Q3 and Q4."

C. October 19, 2021 – Final Disclosure / Materialization of the Risk

244. On October 19, 2021, the relevant truth and foreseeable risks concealed by Defendants' misconduct and their false representations and omissions during the Class Period were fully revealed and/or materialized. On that date, *Politico* published an article, after market hours, entitled: "'They rushed the process': Vaccine maker's woes hamper global inoculation campaign." The *Politico* article reported, in relevant part, that Novavax "faces significant hurdles in proving it can manufacture a shot that meets regulators' quality standards" with respect to NVX-CoV2373. The *Politico* article cited anonymous sources as stating that Novavax's "issues are more concerning than previously understood" and that the Company could take until the end of 2022 to resolve its manufacturing issues and win regulatory authorizations and approvals.

245. Specifically, the *Politico* article reported that Novavax's "delay, which was confirmed by three other people familiar with the discussions between Maryland-based Novavax and the Biden administration, represents a major setback in the effort to vaccinate the world in the wake of new, more transmissible variants." For example, according to the *Politico* article, the Company "has consistently run into production problems," including "[t]he methods it used to test the purity of the vaccine," which "have fallen short of regulators' standards" as Novavax "has not been able to prove that it can produce a shot that is consistently up to snuff, according to multiple people familiar with Novavax's difficulties."

246. The *Politico* article also reported that "[a]lthough Novavax recently attested to some of its analytics and testing issues in a quarterly filing with the [SEC], the [C]ompany's issues are more concerning than previously understood, according to two of the people with direct knowledge of the matter." For example, while "it is generally understood that each [Covid-19] vaccine batch should reach at least 90 percent" in terms of purity levels, Novavax "has struggled to attain anywhere close to that, one of the people with direct knowledge of the situation said,"

and, according to "[a]nother person familiar with the [C]ompany's manufacturing process," the Company "has recently shown purity levels hovering around 70 percent." According to one person that the article quoted with knowledge of the matter, "At some level, I think the efficacy was never going to outweigh the risk associated with the impurity that was in there."

247. Moreover, the *Politico* article revealed that Novavax's manufacturing issues were so severe that they strained global Covid-19 vaccination efforts. For example, with respect to the Covid-19 Vaccines Global Access initiative, also known as COVAX, the *Politico* article found that "[t]he global coalition is already behind on hundreds of millions of planned doses this month" and "is now also at risk of missing its already downgraded 2021 target." The *Politico* article also quoted the director of the Duke Global Health Innovation Center, who stated, "COVAX continues to be challenged for adequate supply . . . in that context, Novavax's manufacturing challenges and delays have been massively disruptive."

248. The *Politico* article also found that Novavax was already aware of specific concerns with NVX-CoV2373's manufacturing process, stating that "senior Trump administration officials on Operation Warp Speed . . . repeatedly warned the [C]ompany that it risked running into problems in scaling up manufacturing of the shot, two people with direct knowledge of those discussions said"; that, "[i]n particular, they worried that Novavax would have difficulty ensuring that the vaccine consistently met the FDA's rigorous quality standards once the vaccine went into mass production—the exact problem that has now stymied the [C]ompany for months"; and that Novavax "rushed the process" and "can't make" the vaccine, according to one of the people with knowledge of the matter.

249. Finally, the *Politico* article revealed that, even as Defendants repeatedly downplayed NVX-CoV2373's manufacturing issues, the U.S. government's confidence in

Novavax's ability to successfully manufacture the drug had waned. For example, the *Politico* article stated that, according to three people with knowledge of the matter, "Novavax's manufacturing problems are seen as far more difficult to fix than the sanitary and design concerns that halted production of J&J's vaccine at the Emergent plant earlier this year."

250. The October 19, 2021 disclosures about Novavax's underlying manufacturing issues and that Novavax was unable to meet FDA criteria needed to file its EUA were foreseeable consequences of, and within the zone of risk concealed by, Defendants' misrepresentations and omissions concerning Novavax's then-current state of its manufacturing processes and capabilities and Novavax's purported alignment with FDA criteria.

251. Moreover, the October 19, 2021 disclosures revealed new information that Defendants' misstatements, omissions, and fraudulent course of conduct previously concealed and/or obscured from the market. These disclosures revealed the relevant truth concealed and/or obscured by Defendants' prior misstatements and omissions surrounding Novavax's underlying manufacturing issues, Novavax's alignment with FDA criteria, and Novavax's ability to file its EUA with the FDA.

252. On this shocking news, the price of Novavax's stock price fell $23.69 per share, or 14.76%, to close at $136.86 per share on October 20, 2021.

253. Analysts understood that the drop in Novavax's stock price was caused by the aforementioned disclosures and revelations. For example, on October 20, 2021, Cantor Fitzgerald explained that "the recent news articles that cited 'anonymous sources' stating Novavax has manufacturing issues that are 'jeopardizing billions of doses earmarked for poor and middle-income countries' . . . has resulted in shares trading down today."

VII. ADDITIONAL INDICIA OF SCIENTER

254. Defendants were active and culpable participants in the fraud, as evidenced by their knowing and reckless issuance and/or ultimate authority over Novavax's and their materially false or misleading statements and omissions. The Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public statements more specifically set forth in Section V, *supra*, were materially false or misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of such statements as primary violators of the federal securities laws. In addition to the specific facts alleged above, Defendants' scienter is further evidenced by the following facts.

A. Defendants Enriched Themselves Through Insider Sales In Advanced of Important Announcements[19]

255. Knowing all along that Novavax would have to delay its EUA filing due to underlying and undisclosed manufacturing issues, Defendants Erck, Trizzino, and Glenn sought to enrich themselves at the expense of Novavax investors. As explained above, Novavax needed to meet certain FDA criteria to file its EUA with the FDA. That is, while Defendants had promised certain dates for when Novavax would file its EUA, if NVX-CoV2373 was not yet meeting those FDA criteria—as was the case—they would have to delay the filing, which they did. And as one analyst, Zacks, explained, "[a]ny delay in the study outcome or any developmental setback for . . . the COVID-19 vaccine candidate will be a major disappointment for the [C]ompany, ***leaving an adverse impact on its shares***." Armed with the knowledge that Novavax's underlying manufacturing issues would require Novavax to announce regulatory filing delays on May 10, 2021 and August 5, 2021, Defendants Erck, Trizzino, and Glenn collectively sold over 100,000

[19] To evaluate the Individual Defendants' selling activity, Lead Plaintiffs used the publicly available trading data that the Individual Defendants are required to report to the SEC on Form 4.

shares, reaping tens of millions of dollars only weeks—and sometimes days—before such announcements.

1. Defendants Erck, Trizzino, and Glenn Sold Large Blocks of Novavax Stock Right Before the EUA Delay Announcements

256. After trading at only $4 per share as of January 2020, Novavax's stock price skyrocketed to almost $240 per share as of the beginning of the Class Period in light of the anticipated potential impact that bringing a successful Covid-19 vaccine to market would have on the Company. As long as the public continued to believe that Novavax had resolved and overcome any manufacturing problems that would prevent its ability to file its EUA, Defendants would be able to prevent Novavax's stock price from falling.

257. However, in reality, even reassurance after reassurance was not able to avoid the inevitable. That is, despite what Defendants told the market, the underlying manufacturing issues prevented Novavax from filing its EUA—requiring Defendants to announce that they were delaying their filing. Thus, knowing that the stock price would take a dive upon the market learning about the delay, Defendants Erck, Trizzino, and Glenn sold a vast number of shares before the announcements.

258. For example, in July 2021, the month leading up to the second partial corrective disclosure and/or materialization of the risk event on August 5, 2021, ***Defendant Erck sold over 100,000 shares of Novavax stock, reaping proceeds of over $22.5 million***. This stands in stark contrast to the zero shares he sold and $0 in stock sale proceeds he earned at the same time the previous year in July 2020. More notable is that Defendant Erck sold off his shares at the same time that the Texas Facility was shut down due to contamination. Indeed, CW 5 confirmed that the facility was at a standstill when Novavax executives unloaded their stock in July 2021.

259. Defendant Glenn carefully timed his Novavax stock sales prior to the first and second partial corrective disclosures and/or materialization of the risk events on May 10, 2021 and August 5, 2021, respectively. In mid-to-late April 2021, Defendant Glenn sold over 8,000 shares of Novavax stock, reaping over $1.6 million in proceeds. Then, in July 2021, he sold over 8,000 additional shares representing proceeds of more than $1.5 million.

260. Furthermore, just days leading up to the first partial corrective disclosure and/or materialization of the risk event on May 10, 2021, Defendant Trizzino sold over 3,000 shares of Novavax stock on May 5 and May 7, earning nearly $600,000 in proceeds.

261. As such, Defendants Erck, Trizzino, and Glenn—knowing that the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain would cause regulatory delays and thus Novavax's stock to drop—enriched themselves before the public found out the truth.

2. Defendants Erck, Trizzino, and Glenn Reaped Massive Proceeds During the Class Period

262. In addition, not only did Defendants Erck, Trizzino, and Glenn carefully time their stock sales at opportune moments right before Novavax's regulatory delay announcements would cause the stock to drop, but they also lined their pockets with massive proceeds throughout the Class Period when Novavax's share price was massively inflated in light of the anticipated potential impact that bringing a successful Covid-19 vaccine to market would have on the Company. Defendants Erck, Trizzino, and Glenn took advantage of the inflated price—knowing all along that the stock would plummet once the public learned the truth.

263. Collectively, Defendants Erck, Trizzino, and Glenn increased their total stock sales by over 33% from 247,326 shares sold during the Control Period to 329,505 shares sold during the

Class Period.[20] The contrast between sales during the Control Period and the Class Period is also striking when measured in dollars. Collectively, ***proceeds from Defendants' sales increased over 118% during the Class Period***, from $29,896,044 million during the Control Period to $65,195,024 million during the Class Period.

264. Individually, Defendants Erck's, Trizzino's, and Glenn's sales also increased during the Class Period. During the Class Period, Defendant Erck sold almost five times as many shares during the Class Period as compared to the number of Novavax shares he sold during the Control Period. Moreover, ***Defendant Erck's proceeds from Novavax sales increased by more than 750% during the Class Period***—from $4,549,253 million during the Control Period to $38,672,789 million during the Class Period. During the Class Period, Defendant Trizzino's proceeds from Novavax sales increased by almost 6%. Similarly, Defendant Glenn's proceeds from Novavax sales increased by over 3.5% during the Class Period.

265. Accordingly, Defendants Erck's, Trizzino's, and Glenn's trading behavior during the Class Period raises a strong inference that it occurred in anticipation of having to disclose the known underlying manufacturing problems related to purity, potency, contamination, scalability, and the supply chain and that such problems were preventing Novavax from filing its EUA—thereby supporting a strong inference of scienter.

B. Manufacturing NVX-CoV2373 Was Critical to Novavax's Core Operations

266. The Individual Defendants' knowledge of the NVX-CoV2373 vaccine manufacturing process and issues related thereto can be inferred because these facts were critical to Novavax's core operations. Indeed, in light of the Company's dismal business prospects

[20] Lead Plaintiffs analyzed the trading by the Individual Defendants during the Class Period and during the similar and equal-length period preceding the Class Period beginning February 24, 2020 to October 19, 2020 (the "Control Period").

immediately preceding the Covid-19 pandemic and lack of revenue or growth, Novavax's potential profits from the NVX-CoV2373 vaccine were crucial to the Company's continued viability.

267. The Company admitted as much at multiple points prior to and throughout the Class Period. For example, in the Company's February 19, 2021 report to the Subcommittee on Oversight and Investigations, U.S. House of Representatives, Committee on Energy and Commerce, Defendant Trizzino explained that "getting this vaccine in the arms of people . . . is our ***priority*** and ***singular goal*** right now. Our team continues to work ***non-stop*** to get NVX-CoV2373 developed, authorized for use and ultimately delivered to vaccination clinics." Similarly, in the Company's 1Q 2021 Form 10-Q, it explained that "[a]t the ***forefront*** of [its] pipeline is NVX-CoV2373."

268. Indeed, the vaccine was of such importance to the Company, and the public at large, that on June 10, 2021, Novavax hosted Maryland Governor Larry Hogan at the site of the Company's planned Vaccines Innovation Campus and global headquarters in Gaithersburg. Additional guests included state, regional, and local officials. Defendants Erck and Glenn personally led the tour, providing an overview of the facility and press briefing.

269. The Texas Facility and North Carolina Facility were also critical to Novavax's development of NVX-CoV2373, and thus the Company's success. For example, Defendant Trizzino himself testified before the Subcommittee on Oversight and Investigations of the U.S. House of Representatives, Committee on Energy and Commerce on February 19, 2021, that the "antigen produced at the Fuji sites in North Carolina and Texas are a critical component of our US supply chain." Likewise, FUJIFILM CEO Martin Meeson referred to FUJIFILM as "a critical partner to Novavax." In fact, FUJIFILM's role was so important to the development of NVX-CoV2373 that then-President Trump toured the North Carolina Facility in July 2020.

270. Defendants further acknowledged that achieving certain purity levels was critical to obtaining regulatory approval of the NVX-CoV2373 vaccine. For example, Novavax stated in its 2Q21 Form 10-Q that "[a]ccepted analytical methods that we can use to demonstrate our vaccine's purity, potency and consistent lot manufacturing are ***critical*** to attaining licensure in all the territories we intend to sell."

271. Analysts following Novavax also understood that the NVX-CoV2373 vaccine was critical to the Company's success. For example, on April 15, 2021, CFRA issued a report stating that "[w]e think the future financial success of NVAX and its ability to record a positive bottom-line result is highly dependent on successful approvals and rapid commercialization of its Covid-19 vaccine" and "the main focus of the [C]ompany is on its NVX-CoV2373 vaccine candidate against Covid-19." Similarly, on April 28, 2021, Zacks issued a report stating that "any developmental setback for . . . the COVID-19 vaccine candidate will be a major disappointment for the [C]ompany, leaving an adverse impact on its shares." On June 14, 2021, Jefferies issued a report explaining that the "[k]ey to [Novavax] will be their ability to execute on filing their data to the various regulatory agencies for EUA approval, ability to manufacture doses of their vaccine, and procure additional contracts." As the Class Period progressed, and Defendants continued to delay the release of the vaccine, analysts reiterated that the release of the NVX-CoV2373 vaccine was key to the Company's success. For example, on August 6, 2021, Jeffries issued a report, which stated that "[i]nvestors went into Q2 EPS w/ two key questions 1) what's the status of the EUA filings and 2) has vaccine manufacturing improved[.]"

272. Moreover, before the Covid-19 pandemic, and the resulting capital influx from government incentives to manufacture the NVX-Co2372 vaccine, Novavax was in dire straits. After a previous failed attempt to produce a commercially viable vaccine, the Company was in

danger of being delisted from the NASDAQ and was forced to sell its manufacturing facilities to avoid going out of business. By January 2020, the Company had barely enough cash left to survive for six months, and its market value was a paltry $127 million. Indeed, the $388 million investment by CEPI was over three times the Company's then-market value and the $1.6 billion awarded to Novavax by the federal government was over twelve times the Company's pre-pandemic value. However, during the Class Period, as Defendants misleadingly assured the market of the NVX-CoV2373 vaccine's imminent roll out, the Company's market value surged to as much as $11 billion.

273. Given the importance of the NVX-CoV2373 vaccine to Novavax's business, knowledge of the manufacturing problems associated with the vaccine, including the fact that Novavax was unable to produce a vaccine of sufficient quality to meet regulatory requirements, can therefore be imputed to the Individual Defendants.

C. Defendants' Personal Involvement in NVX-CoV2373's Development Supports That They Had Actual Knowledge or Were Reckless in Not Knowing About the Manufacturing Problems

274. The Individual Defendants were responsible for Novavax's efforts to manufacture the NVX-CoV2373 vaccine in conformance with FDA regulations, including through personally communicating with the FDA and overseeing the manufacturing process, supporting a strong inference of scienter.

275. Indeed, there is no question that the Individual Defendants were directly and personally involved in Novavax's efforts to manufacture a quality vaccine. cGMP regulations and multiple CWs confirm and corroborate that Novavax was aware of the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain throughout the Class Period.

276. For example, cGMP regulations required Novavax to apprise itself of any manufacturing problems, even where another company was actually manufacturing the vaccine. Novavax was also "responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company," such as FUJIFILM or any other manufacturing partner. Additionally, with respect to any "reports of inspectional observations issued by the [FDA], or any regulatory actions relating to good manufacturing practices brought by the [FDA]," or any investigations into complaints involving the "possible failure of a drug product to meet any of its specifications," cGMP regulations required that the manufacturing company provide Novavax with written notice of the issue. In addition, cGMP regulations required Novavax to maintain laboratory records, including information relating to "results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested."

277. Thus, Novavax was aware of the particular issues that the FDA raised in connection with the FDA's investigations into the North Carolina Facility and Texas Facility, which highlighted a litany of quality issues outlined above. In fact, the FDA's very own reports support this conclusion, as it indicated that FUIJIFILM was required to notify the client (which CW 5 confirmed was Novavax) of deviations and OOS results within two business days. In fact, with respect to issues of contamination, CW 5 specifically stated that a client, who was Novavax in this case, must be notified about a contamination within 24 to 48 hours of its discovery.

278. Likewise, former employees from the Texas Facility and North Carolina Facility recalled that Novavax was notified about the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain that occurred throughout the Class Period. For example, according to CW 5, Novavax had two Novavax's Onsite Employees at the Texas Facility.

Indeed, CW 5 explained that CW 5 and the Texas Facility Director of Manufacturing CW 6 communicated with the two Novavax's Onsite Employees "every single day" regarding manufacturing and the results of quality checks, which CW 5 recalled were conducted every 24 to 48 hours.

279. CW 5 recalled that Novavax's Onsite Employees were notified about each contamination issue that occurred at the Texas Facility throughout the Class Period. That is, they were notified about the four contamination incidents that led to delays in manufacturing that started in December 2020. CW 5 even recalled that Mr. Hash, one of Novavax's Onsite Employees, was involved in the investigations into the contaminations. CW 5 recalled that there were phone calls and emails about contaminations and delays from Mr. Hash to Novavax headquarters, including Novavax's Quality Assurance department.

280. Similarly—and with respect to a particular viral contamination that occurred in March 2021 and ultimately shut down the Texas Facility's manufacturing processes until at least September 2021—CW 5 confirmed that everything to do with the viral contamination was "communicated to" Novavax's Onsite Employees as the discovery and investigation progressed, along with daily calls with Novavax personnel in Maryland.

281. CW 6 similarly recalled that Novavax had some employees who worked onsite at the Texas Facility, including Mr. Hash, along with a few other Novavax employees who rotated onsite "off-and-on." CW 6 further recalled that CW 6 participated on Zoom calls "every day" with Novavax's Onsite Employees, a Novavax employee at Novavax's headquarters in Maryland named Ivailo, and other Novavax employees from different departments. According to CW 6, Novavax's Onsite Employees, Ivailo, and the other Novavax employees "knew everything that we were doing." CW 6 further advised that there were typically 10 Novavax employees on the calls.

282. Likewise, CW 7—a former Manager, Quality Assurance for the North Carolina Facility—recalled that any problems were constantly communicated to Novavax, which had someone onsite at the North Carolina Facility weekly at a minimum. Moreover, CW 7 recounted that all testing results for batches at the North Carolina Facility were communicated to Novavax through a "batch record," which relayed to Novavax that testing was completed and the results of the testing. CW 7 even explained that FUJIFILM sometimes changed the vaccine manufacturing materials given certain supply chain issues, and that Novavax would have to approve all the changes. CW 7 also recalled that Novavax had teams of people from departments including quality and technical who were involved in any modifications. CW 7 further explained that Novavax was involved with "everything" and was "driving" the way in which FUJIFILM manufactured the product. In fact, CW 7 advised that the level of Novavax's involvement was unlike anything she had previously encountered at FUJIFILM, meaning that Novavax was more involved in the manufacturing process than other clients at FUJIFILM.

283. Additionally, Defendant Erck was also personally and directly involved in the manufacturing process's progress. For instance, according to multiple CWs, Defendant Erck held Company-wide meetings with Novavax employees to discuss the regulatory process for the NVX-CoV2373 vaccine. CW 2 recalled that Defendant Erck and Novavax's leadership team spoke to employees and facilitated Q&A sessions during Company-wide meetings that happened at least once a quarter. At these meetings, CW 2 recalled that Defendant Erck discussed the topic of seeking regulatory approval.

284. Similarly, CW 1 recalled that Defendant Erck spoke to employees during monthly Company-wide meetings that included Q&A sessions, with employees able to submit questions in advance via an app. CW 1 further recalled that the Q&A sessions included discussions about

employees' concerns in regard to "our manufacturing capabilities" and "the likelihood of being able to manage all those stakeholders," in addition to concerns over whether Novavax would "be able to get our stability information stabilized." CW 4 also corroborated this information, stating that Defendant Erck spoke to employees during Company-wide, town hall-style meetings that included a Q&A session, with employees being able to submit questions in advance using an app.

285. CW 4 explained that if there were issues in getting a trial started, those problems would be brought to Chief Medical Officer Filip Dubovsky and Defendant Erck. CW 4's understanding of how such information would have flowed up the chain of command at Novavax was that manufacturing issues were brought to Dubovsky's attention, that Dubovsky would have discussed it with Defendant Erck who in turn would have discussed it with Defendant Glenn, and that Defendant Erck—or sometimes Defendant Glenn—had to bring it to the attention of Novavax's Board of Directors.

286. Furthermore, Defendant Erck had access to reports that contain hundreds of pages of data from Novavax's manufacturing sites. For example, CW 1 explained that Novavax submitted documents containing information from the Company's manufacturing sites that was then submitted to the FDA in the form of Module 3 Quality reports. CW 1 further explained that "those are the documents we were working on the hardest," and that "Novavax really needed to have [its] CMC module in line before we could get that emergency use authorization." CW 1 recalled that these reports consisted of "hundreds of pages."

287. CW 1 explained that the content from the manufacturing sites that was detailed in the Module 3 reports involved drug and product information and data. CW 1 further explained that the Module 3 reports were submitted to the FDA via the agency's ESG and sometimes via email, depending on the preferences of the two or three FDA project managers with whom

Novavax worked. CW 1 recalled that Director – Regulatory Affairs Kathleen Callahan would send such emails and handled all communications with the FDA. CW 1 also explained that Novavax stored the Module 3 reports on an internal system managed by the Quality department.

288. Further, CW 7 recounted that the vaccine's purity levels were manufactured according to information provided by and processes approved by Novavax. As mentioned above, CW 1 explained that FDA concerns were also discussed at weekly, and sometimes daily, Regulatory Affairs team meetings.

289. Defendants Erck and Glenn personally led a tour of the Company's planned Vaccines Innovation Campus and global headquarters in Gaithersburg for Governor Hogan, providing an overview of the facility and a press briefing.

290. Defendants' direct involvement in the vaccine manufacturing process thus supports a strong inference of scienter.

D. Defendants' Statements Themselves Support Scienter

291. Throughout the Class Period, Defendants spoke repeatedly on Novavax's ability to manufacture and commercialize the NVX-CoV2373 vaccine, leading investors to believe that nothing stood in the way of Novavax producing the vaccine at the quality required by FDA and cGMP regulations while omitting that the Company was having substantial issues developing a consistently pure vaccine on a large scale. These false and misleading statements themselves provide a strong inference that Defendants were aware of or, at the very least, were reckless in not knowing that Novavax was unable to produce a vaccine of sufficient quality to satisfy governmental regulations. Accordingly, Defendants breached their duty under the federal securities laws by speaking about these topics and failing to fully disclose all relevant material information while doing so.

292. For instance, on February 24, 2021, in an interview with *The Washington Post*, Defendant Glenn confidently assured investors that "we lined up—FDA gave advice on how to do a trial, what success means, and that really was accepted by the world, if you will, and ***so we're aligned up with those success criteria in all of our trials***."

293. Defendants made similar assurances throughout the Class Period. On May 10, 2021, Defendant Erck misleadingly assuaged the market's concerns about the delay in releasing the NVX-CoV2373 vaccine stating that "***nearly all of the major challenges have been overcome and we can clearly see the light at the end of the tunnel***." On August 5, 2021, a *Reuters* article reported that Defendant Erck stated, "***[w]e appear to have got past (certain) supply issues and are now being able to produce at scale***." On September 21, 2021, in response to a reporter's question about transparency, Defendant Trizzino explained that "[t]his transparency is important. ***And we've been extremely transparent across multiple fronts. All of our clinical data has been shared very quickly***."

294. Defendants' repeated assurances to investors that Novavax was able to produce a vaccine of sufficient quality to meet regulatory standards—when they had been apprised of the multiple manufacturing problems as previously described—demonstrate that they ***either*** knew that the Company was experiencing substantial manufacturing problems related to purity, potency, contamination, scalability, and the supply chain, which delayed the approval of the NVX-CoV2373 vaccine, ***or*** were reckless in not knowing or investigating that this was the case. In either scenario, there is a strong inference that Defendants made these statements with scienter.

E. Government's Crackdown on Emergent BioSolutions Further Supports Scienter

295. Like Novavax, other companies producing vaccines to combat Covid-19 were subject to the FDA regulations concerning vaccine quality standards. Indeed, these FDA

regulations, and the FDA's willingness to enforce them, were widely known in the industry. Novavax even acknowledged this in its 2021 Form 10-K: "The development, production and marketing of biological products, which include the vaccine candidates being developed by Novavax or our collaborators, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries."

296. Moreover, Defendants were able to see the regulatory process play out firsthand in connection with one of its manufacturing partners, Emergent. While Defendants were touting their purported alignment with the FDA criteria and transparency, federal regulators halted production at Emergent's Baltimore facility in April 2021 for more than three months until the company resolved quality control problems, including failure to prevent contamination that ruined tens of millions of doses and other cGMP violations. The facility had produced Johnson & Johnson's and AstraZeneca's vaccines, but as a result of the issues, the facility now manufactures doses only for Johnson & Johnson.

297. The FDA's crackdown on Emergent's manufacturing facility served as a reminder—and a warning—to other pharmaceutical companies producing vaccines for Covid-19. Though there was an urgent need for these vaccines, the FDA would not show leniency or allow a company to cut corners in producing a vaccine—especially one so critical to the public welfare. It was thus of utmost importance for companies—such as Novavax—to ensure that their manufacturing facilities complied with all cGMP and met the requisite FDA criteria needed for ultimate approval. Indeed, as a pharmaceutical company, a core aspect of Novavax's business is ensuring compliance with manufacturing quality standards for each jurisdiction in which it manufacturers its vaccines.

298. As a result of this well-known trend that FDA enforcement was focusing on vaccine manufacturers' quality control, Defendants knew or were reckless in not knowing that they needed to verify the truth of their statements about the Company's ability to manufacture a vaccine of sufficient quality to meet FDA and cGMP standards.

VIII. CONTROL PERSON ALLEGATIONS

299. The Individual Defendants, by virtue of their high-level and controlling positions at Novavax, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information about the Company, its business, operations, internal controls, growth, financial statements, and financial condition as alleged herein. As set forth below, the materially misstated information conveyed to the public was the result of the collective actions of these individuals.

300. Defendants Erck, Covino, Trizzino, and Glenn, as senior executive officers of Novavax—a publicly-held company whose common stock was, and is, traded on the NASDAQ, and governed by the federal securities laws—had a duty to disseminate prompt, accurate, and truthful information with respect to the Company's business, operations, internal controls, growth, financial statements, and financial condition, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Novavax's publicly traded common stock would be based on accurate information. Each of the Individual Defendants violated these requirements and obligations during the Class Period.

301. Defendants Erck, Covino, Trizzino, and Glenn, because of their positions of control and authority as senior executive officers of Novavax, were able to and did control the content of Novavax's SEC filings, press releases, and other public statements issued by or on behalf of Novavax during the Class Period. Each would have been provided with copies of the statements

made in the SEC filings at issue in this action before they were issued to the public and would have had the ability to prevent their issuance or cause them to be corrected. Accordingly, the Individual Defendants were responsible for the accuracy of the public statements alleged herein.

302. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Novavax common stock by disseminating materially false and misleading information and concealing and omitting material adverse facts. The scheme deceived the investing public regarding Novavax's business, operations, and management, and the intrinsic value of Novavax's common stock, and caused Lead Plaintiffs and members of the Class to purchase Novavax common stock at artificially inflated prices.

IX. CLASS ACTION ALLEGATIONS

303. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons and entities who or which purchased or otherwise acquired the publicly traded common stock of Novavax during the Class Period and were damaged thereby. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer or director of Novavax during the Class Period; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; (v) Novavax's employee retirement and benefit plan(s) and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person.

304. The members of the Class are so numerous that joinder of all members is impracticable. According to public reports filed with the SEC, during the Class Period, Novavax had over 70 million outstanding shares of common stock and was actively traded on the NASDAQ

under the ticker symbol "NVAX." While the exact number of Class members is unknown to Lead Plaintiffs at this time, and such number can only be ascertained through appropriate discovery, Lead Plaintiffs believe that the proposed Class has thousands of members and is widely dispersed geographically. Record owners and other members of the Class may be identified from records maintained by Novavax and/or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

305. Lead Plaintiffs' claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' allegedly wrongful conduct in violation of the Exchange Act as complained of herein.

306. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class. Lead Plaintiffs have retained counsel competent and experienced in class and securities litigation.

307. Common questions of law and fact exist as to all members of the Class and predominate over questions solely affecting individual members of the Class. The questions of law and fact common to the Class include, but are not necessarily limited to, the following:

(a) Whether Defendants violated the federal securities laws by their acts and omissions alleged herein;

(b) Whether the statements Defendants made to the investing public during the Class Period contained material misrepresentations or omitted to state material information;

(c) Whether, and to what extent, the market price of Novavax common stock was artificially inflated during the Class Period because of the material misstatements alleged herein;

(d) Whether Defendants acted with the requisite level of scienter;

(e) Whether the Individual Defendants were controlling persons of Novavax; and

(f) Whether the members of the Class have sustained damages as a result of the conduct complained of herein, and if so, the proper measure of such damages.

308. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

309. To the extent that Lead Plaintiffs allege that Defendants made affirmative misstatements, Lead Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's securities traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities;

(e) Lead Plaintiffs and other members of the Class purchased Novavax's securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts;

(f) Novavax's common stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(g) as a regulated issuer, Novavax filed periodic public reports with the SEC and the NASDAQ;

(h) Novavax regularly communicated with public investors via established market communication mechanisms, including regular dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(i) Novavax was followed by numerous securities analysts employed by major brokerage firms including, but not limited to, B. Riley Securities, Inc., Cantor Fitzgerald & Co., Cowen, H.C. Wainwright & Co., LLC, Jefferies LLC, Zacks, and J.P. Morgan Chase & Co., all of which wrote reports that were distributed to the sales force and certain customers of their respective brokerage firm(s) and that were publicly available and entered the public marketplace.

310. As a result of the foregoing, the market for Novavax's securities promptly digested current information regarding Novavax from publicly available sources and reflected such information in Novavax's securities price(s). Under these circumstances, all persons and entities who or which purchased or otherwise acquired Novavax common stock during the Class Period suffered similar injuries through their purchase of Novavax common stock at artificially inflated prices and thus, the presumption of reliance applies.

311. The material misrepresentations and omissions alleged herein would induce a reasonable investor to misjudge the value of Novavax common stock.

312. Without knowledge of the misrepresented or omitted material facts alleged herein, Lead Plaintiffs and other members of the Class purchased shares of Novavax common stock

between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.

313. To the extent that Defendants concealed or improperly failed to disclose material facts with respect to Novavax's business, Lead Plaintiffs are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

XI. NO SAFE HARBOR

314. The statutory safe harbor provided by the PSLRA for forward-looking statements under certain circumstances does not apply to any of the materially false and misleading statements alleged in this pleading. First, many of the statements alleged to be false and misleading relate to historical facts or existing conditions. Second, to the extent any of the allegedly false and misleading statements may be characterized as forward-looking, they were not adequately identified as "forward-looking" statements when made. Third, any purported forward-looking statements were not accompanied by meaningful cautionary language because the risks that Defendants warned of had already come to pass.

315. To the extent any statements alleged to be false and misleading may be construed to discuss future intent, they are mixed statements of present or historical facts and future intent and are not entitled to PSLRA safe-harbor protection—at least with respect to the part of the statement that refers to the present.

316. In addition, the PSLRA imposes an additional burden on oral forward-looking statements, requiring Defendants to include a cautionary statement that the particular oral statement is a forward-looking statement, and that "actual results might differ materially from those projected in the forward-looking statement." 15 U.S.C. § 78u-5(c)(2)(A)(i)-(ii). Defendants failed to both identify certain oral statements as forward-looking and include the cautionary language required by the PSLRA.

317. Furthermore, Defendants did not accompany their statements with meaningful cautionary language identifying important factors that could cause actual results to differ materially from any results projected. To the extent Defendants included any cautionary language, that language was not meaningful because any potential risks identified by Defendants had already passed or manifested. As detailed herein, Defendants failed to disclose to the market that, throughout the Class Period, Novavax was experiencing multiple manufacturing problems and delays that prevented NVX-CoV2373 from meeting FDA criteria and thus causing multiple regulatory delays with respect to Novavax's ability to file its EUA with the FDA.

318. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, or the forward-looking statement was authorized or approved by an executive officer of Novavax who knew that the statement was false when made.

XII. CAUSES OF ACTION

COUNT I

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(b) Promulgated Thereunder Against Novavax and the Individual Defendants

319. Lead Plaintiffs repeat and re-allege the above paragraphs as though fully set forth herein.

320. This Count is asserted pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC against Novavax and the Individual Defendants.

321. As alleged herein, throughout the Class Period, Novavax and the Individual Defendants, individually and in concert, directly and indirectly, by the use of the means or

instrumentalities of interstate commerce, the mails and/or the facilities of national securities exchanges, made untrue statements of material fact and/or omitted to state material facts necessary to make their statements not misleading and carried out a plan, scheme and course of conduct, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Novavax and the Individual Defendants intended to and did, as alleged herein, (i) deceive the investing public, including Lead Plaintiffs and members of the Class; (ii) artificially inflate and maintain the price of Novavax common stock; and (iii) cause Lead Plaintiffs and members of the Class to purchase Novavax common stock at artificially inflated prices.

322. The Individual Defendants were individually and collectively responsible for making the false and misleading statements and omissions alleged herein and having engaged in a plan, scheme, and course of conduct designed to deceive Lead Plaintiffs and members of the Class, by virtue of having made public statements and prepared, approved, signed, and/or disseminated documents that contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

323. As set forth above, Novavax and the Individual Defendants made their false and misleading statements and omissions and engaged in the fraudulent activity described herein knowingly and intentionally, or in such a deliberately reckless manner as to constitute willful deceit and fraud upon Lead Plaintiffs and the other members of the Class who purchased Novavax common stock during the Class Period.

324. In ignorance of the false and misleading nature of Novavax's and the Individual Defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for Novavax common stock, Lead Plaintiffs and other members of the Class purchased Novavax common stock at artificially inflated prices during the

Class Period. But for the fraud, Lead Plaintiffs and members of the Class would not have purchased Novavax common stock at such artificially inflated prices. As set forth herein, when the true facts were subsequently disclosed, the price of Novavax common stock declined precipitously, and Lead Plaintiffs and members of the Class were damaged and harmed as a direct and proximate result of their purchases of Novavax common stock at artificially inflated prices and the subsequent decline in the price of that security when the truth was disclosed.

325. By virtue of the foregoing, Novavax and the Individual Defendants are liable to Lead Plaintiffs and members of the Class for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

For Violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5(a) and (c) Promulgated Thereunder Against Novavax and the Individual Defendants

326. Lead Plaintiffs repeat and re-allege every allegation set forth above as if fully set forth herein.

327. This Count is brought solely and exclusively under the provisions of Rule 10b-5(a) and (c). Accordingly, Lead Plaintiffs need not allege in this Court nor prove in this case that any of the Defendants made any misrepresentations or omissions of material fact for which they may also be liable under Rule 10b-5(b) and/or any other provisions of law.

328. During the Class Period, Defendants carried out a common plan, scheme, and unlawful course of conduct that was intended to, and did: (i) deceive the investing public, including Lead Plaintiffs and the Class; (ii) artificially inflate the price of Novavax common stock; and (iii) cause Lead Plaintiffs and members of the Class to purchase Novavax common stock at artificially inflated prices.

329. In furtherance of this unlawful plan, scheme and course of conduct, Defendants employed devices, schemes and artifices to defraud, and knowingly and/or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Lead Plaintiffs and the Class in connection with their purchases of Novavax common stock, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder.

330. Defendants' fraudulent devices, schemes, artifices and deceptive acts, practices, and course of business included the knowing and/or reckless suppression and concealment of the manufacturing problems related to purity, potency, contamination, scalability, and the supply chain that Novavax was experiencing throughout the Class Period, which prevented the Company from filing its EUA with the FDA. By concealing such problems from investors, and in fact explicitly reassuring investors that any prior problems that NVX-CoV2373's manufacturing process may have faced were resolved, Defendants were able to take advantage of Novavax's inflated stock price at opportune moments throughout the Class Period before the market learned the truth.

331. For example, given how important it was for the Company to file its EUA and bring NVX-CoV2373 to market, it was evident that any delays or issues that prevented Novavax from doing so would cause Novavax's stock price to drop. To be sure, an analyst, Zacks, explained, "[a]ny delay in the study outcome or any developmental setback for . . . the COVID-19 vaccine candidate will be a major disappointment for the [C]ompany, leaving an adverse impact on its shares."

332. Furthermore, because Defendants were aware of the manufacturing problems explained above, Defendants knew that Novavax would have to delay its EUA filing. As such, knowing that the stock price would take a dive upon the market learning about the delay, Defendants Erck, Trizzino, and Glenn carefully planned the timing of their stock sales in the

weeks, and sometimes days, before announcing a delay. As a result of their continued reassurances and omissions throughout the Class Period, Defendants Erck, Trizzino, and Glenn collectively made over $65 million in proceeds during the Class Period—more than a 118% increase from the year prior.

333. Lead Plaintiffs and the Class reasonably relied upon the integrity of the market in which Novavax's common stock traded.

334. During the Class Period, Lead Plaintiffs and the Class were unaware of Defendants' fraudulent scheme and unlawful course of conduct and/or the impact of the fraudulent scheme. Had Lead Plaintiffs and the Class known the true extent of Defendants' unlawful scheme and unlawful course of conduct, they would not have purchased Novavax's common stock, or if they had, would not have done so at the artificially inflated prices paid for such securities.

335. As a direct and proximate result of Defendants' scheme to defraud and such unlawful course of conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of Novavax common stock during the Class Period.

336. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rules 10b-5(a) and (c) promulgated thereunder and are liable to Lead Plaintiffs and the Class for damages suffered in connection with their purchases of Novavax common stock during the Class Period.

COUNT III

Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

337. Lead Plaintiffs repeat and reallege the above paragraphs as though fully set forth herein.

338. This Count is asserted pursuant to Section 20(a) of the Exchange Act against the Individual Defendants.

339. The Individual Defendants had control over Novavax and made the materially false and misleading statements and omissions on behalf of Novavax within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their executive leadership positions and positions as directors of Novavax, as alleged above, the Individual Defendants had the power to influence and control and did, directly or indirectly, influence and control the decision making of the Company, including the content and dissemination of the various statements which Lead Plaintiffs contend were false and misleading. The Individual Defendants were provided with or had unlimited access to the Company's internal reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or cause them to be corrected.

340. In particular, the Individual Defendants had direct involvement in and responsibility over the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein.

341. By reason of such wrongful conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of the Company's shares during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for judgment as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure, and appointing Lead Plaintiffs' counsel as Lead Counsel for the Class;

B. Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

C. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Lead Plaintiffs demand a trial by jury.

Dated: March 11, 2022

Respectfully Submitted,

LABATON SUCHAROW LLP

/s/ James W. Johnson
James W. Johnson (admitted *pro hac vice*)
Michael H. Rogers (admitted *pro hac vice*)
David J. Schwartz (*pro hac vice* forthcoming)
James T. Christie (admitted *pro hac vice*)
140 Broadway
New York, NY 10005
Tel: (212) 907-0700
Fax: (212) 818-0477
Email: jjohnson@labaton.com
mrogers@labaton.com
dschwartz@labaton.com
jchristie@labaton.com

POMERANTZ LLP
Brian Calandra (admitted *pro hac vice*)
Jeremy A. Lieberman (*pro hac vice* forthcoming)
600 Third Avenue, 20th Floor
New York, NY 10016
Tel: (212) 661-1100
Fax: (212) 661-8665
Email: bcalandra@pomlaw.com
jalieberman@pomlaw.com

Counsel for Co-Lead Plaintiffs and Lead Counsel for the Class

COHEN MILSTEIN SELLERS & TOLL PLLC

/s/ Steven J. Toll
Steven J. Toll (Md. Bar No. 15824)
Daniel S. Sommers (Md. Bar No. 15822)
S. Douglas Bunch
1100 New York Avenue N.W.
Suite 500, East Tower
Washington, DC 20005
Tel: (202) 408-4600
Fax: (202) 408-4699
Email: stoll@cohenmilstein.com
dsommers@cohenmilstein.com
dbunch@cohenmilstein.com

Local Counsel for Co-Lead Plaintiffs

PORTNOY LAW FIRM
Lesley F. Portnoy
1800 Century Park East, Suite 600
Los Angeles, California 90067
Tel: (310) 692-8883
Email: esley@portnoylaw.com

Additional Counsel for Co-Lead Plaintiffs and the Class